Immobilization of the spine, an evaluation of the National Protocol Ambulance 8

An observational quantitative cross-sectional study

Name:	I. Oving
Student number:	5487501
Status:	Final
Date:	27/6/2016
Education:	Utrecht University, Master Clinical Health Sciences, Nursing sciences
Research Institute:	UMC Utrecht
Supervisor:	Prof. dr. L.P.H. Leenen , Dr. H.W. Blom-Ham
Course instructor:	Dr. H. van Os- Medendorp
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Abstract (English)

Background In 2015, the National Protocol Ambulance version 7 (LPA7) revised to version 8 (LPA8). The patient profile, including criteria to assess which patient is suspected of having spinal injury, was too strict in LPA7. Therefore, the patient profile in LPA8 includes less strict criteria. It is unclear whether criteria in LPA8 indicate the correct patients suspected of having spinal injury. Moreover, complications occurred after using spinal immobilization methods and devices in LPA7. Therefore, other methods and devices are included in LPA8.

Objectives To describe the patient profile according to LPA7 and the diagnosis of spinal(cord)injury in trauma patients with suspected spinal injury admitted to the trauma room of the emergency department and to evaluate used spinal immobilization methods and devices as applied by paramedics according to the LPA8.

Methods During observations at the trauma room of the emergency department, a questionnaire, designed by the researcher, was completed by the researcher or trauma nurses for adult trauma patients admitted to an academic hospital.

Results All 31 patients included, met ≥1 criteria in LPA7. In five patients, not immobilized during transport, spinal injury was not present. Patients were immobilized lying or half-sitting with devices as the backboard, vacuum mattress, stretcher, head blocks and/or a C-collar. For 24 patients, extra devices were applied at the emergency department.

Conclusion Although all patients met ≥1 criteria in LPA7, not every patient was immobilized during transport. Spinal injury was not present in patients without immobilization. Moreover, varying immobilization methods are used and discrepancies in immobilization between the pre-hospital and hospital phase are showed.

Implications of key findings Discrepancies between the pre-hospital and hospital phase should be reduced to prevent confusion between health care professionals. Moreover, research according to specificity and sensitivity of criteria inLPA8 is recommended.

Keywords Spinal (cord) injury, immobilization, trauma patients, emergency department

Abstract (Dutch)

Achtergrond In 2015 is het Landelijk Protocol Ambulancezorg versie 7 (LPA7) herzien naar versie 8 (LPA8). Het patiënten profiel, welke beslissingscriteria bevat om te bepalen welke patiënt is verdacht op wervelletsel, was te streng in LPA7. LPA8 bevat daarom minder strenge beslissingscriteria. Het is nog onduidelijk of deze criteria de juiste patiënt indiceren. Tevens traden er complicaties op door gebruik van immobilisatiemethoden in LPA7. Er zijn daarom andere immobilisatiemethoden toegevoegd in LPA8.

Doelen Het beschrijven van het patiënten profiel volgens LPA7 en de diagnose ten aan zien van wervel(kolom)letsel bij trauma patiënten met verdenking op wervelletsel die naar de trauma kamer op de eerste hulp zijn getransporteerd en het evalueren van de door ambulance verpleegkundigen aangebrachte immobilisatiemethoden volgens LPA8.

Methode Tijdens observaties op de spoedeisende hulp werd een vragenlijst, opgesteld door de onderzoeker, ingevuld door de onderzoeker of door spoedeisende hulp verpleegkundigen voor volwassen trauma patiënten die naar een academisch medisch centrum zijn gebracht.

Resultaten Alle 31 geïncludeerde patiënten voldeden aan ≥1 criteria in LPA7. Wervelletsel was niet aanwezig bij alle vijf de patiënten die niet waren geïmmobiliseerd tijdens transport. Patiënten werden liggend of halfzittend geïmmobiliseerd met een backboard, vacuümmatras, brancard, head blocks en/of een nek-kraag. Voor 24 patiënten werden extra immobilisatiemethoden aangebracht op de spoedeisende hulp .

Conclusie Ondanks dat alle patiënten voldeden aan ≥1 criteria in LPA7 zijn niet alle patiënten geïmmobiliseerd. Geen van de niet geïmmobiliseerde patiënten werd gediagnosticeerd met wervelletsel. Verder werd er gebruik gemaakt van verschillende immobilisatie methoden en zijn er discrepanties te zien ten aanzien van immobilisatie tussen de pre-hospitaal en hospitaalfase .

Implicaties van kernbevindingen Verschillen tussen de pre-hospitaal en hospitaalfase moeten worden gereduceerd om verwarring tussen professionals in de gezondheidszorg te voorkomen. Verder wordt onderzoek naar de specificiteit en sensitiviteit van beslissingscriteria in LPA8 aanbevolen.

Kernwoorden Wervel(kolom)letsel, immobilisatie, trauma patiënten, eerste hulp.

Introduction

Trauma is defined as injuries to humans' tissue or organs, resulting from energy imparted from the environment.[1] Trauma patients are admitted to the trauma room of an emergency department (ED) if they need medical help.[2] The number of trauma patients treated at the ED in the Netherlands was 840.000 in 2011.[1]

Trauma patients with high-energetic mechanisms of injury, such as high-speed traffic accidents, are often suspected of having *spinal injury*.[3] Spinal injury is defined as fractures or lesions in the ligaments of the spine.[3] The probability of spinal injury after a trauma increases with age.[4] It is questionable whether the severity of the patient's injury plays a role in the presence of spinal injury.[5]

The spinal cord of trauma patients suspected of having spinal injury is immobilized with spinal immobilization methods and devices during transport to protect against spinal movement. Spinal movement could lead spinal injury into *spinal cord injury* (SCI) because it makes fractures of the spine unstable.[6-7] SCI is defined as damage to the spinal nerves resulting in a change, either temporary or permanent, in its sensory or motoric function.[3] Damage can occur to the cervical, thoracic, or lumbar nerves.[3]

The incidence of SCI varies between 10.4 and 83 per million worldwide and is relatively low (10.4 per million) in the Netherlands.[6] SCI, however, has a high impact on the patient's life due to long rehabilitation processes and additional events, such as bio-psychological and social-economic impacts.[7]

To assess which trauma patient is suspected of having spinal injury, clinical decision criteria are developed. Until recently, the used clinical decision criteria for the pre-hospital phase in the Netherlands were described in the National Protocol Ambulance 7 (LPA7).[8] Every trauma patient who met ≥1 decision criteria of the patient profile in LPA7 was immobilized. A patient profile describes decision criteria based on characteristics of the trauma mechanism and (suspected) injury of the patient. The patient profile in LPA7 was divided into four decision criteria. The first decision criterion was "whether the trauma patient is intubated." The second decision criterion was "the Glascow Coma Scale is <15." The third decision criterion was "indicators according to the mechanism of spinal injury," and the fourth decision criterion was "criteria according to the suspected injury of the trauma patient".[8] The use of these strict clinical decision criteria increased unnecessary spinal immobilization.[8-9]

Immobilization devices used in LPA7 were the backboard, cervical-collar (C-collar), and lateral head blocks.[8] Although these devices immobilize the spine to prevent SCI, major complications for trauma patients occurred when using devices according to LPA7. Examples are back-ache and headache,[10] decubitus,[10-11] and discomfort and anxiety.[10-11]

These complications and unnecessary spinal immobilizations led to the revision of LPA7[8] to LPA8[12] in January 2015. The revision is based on eleven scientific literature references[13-23] in which the level of evidence was low. Five references were based on consensus;[14-18] one international guideline is cited;[13] and two other references were only based on pre-hospital care in children.[19-20] Despite the low level of evidence for LPA7, as well, the revision to LPA8 is questionable.[11]

The revision included two major changes for spinal immobilization. The first change altered the decision criteria of the patient profile, and the second change included the use of other immobilization methods and devices. Regarding the first change, the patient profile in LPA8 includes less strict decision criteria. Only two decision criteria are used. The first decision criterion is **"**every mechanism of injury wherein suspected for spinal injury," and the second decision criterion is "criteria according to the suspected injury of the trauma patient." The decision to immobilize the trauma patient in LPA8 is now more based on individual consideration.[11-12] Furthermore, in the hospital phase (after the trauma patient is admitted to the ED), stricter decision criteria are used than in LPA8[11, 24-25]. Due to this discrepancy, many trauma patients not immobilized during transport are immobilized at the ED.[11]The second change includes the use of other immobilization methods and devices.[12] In LPA8, the following methods and devices are described: the patient can be admitted lying or sitting on a stretcher combined with head blocks, on the backboard, or on the vacuum mattress.[12] It is unknown when the C-collar is used.[11-12]

Because the revision of LPA7 to LPA8 is questionable, it is necessary to describe the patient profile of admitted trauma patients suspected of having spinal injury according to LPA7, whether they are or are not immobilized, and their final diagnoses regarding spinal injury and SCI. Whether decision criteria in LPA8 indicate the correct patients suspected of having spinal injury can then be discussed. Furthermore, evaluation of the used immobilization methods and devices described in LPA8 is necessary.

OBJECTIVES

1) To describe the patient profile according to LPA7 and the diagnosis of spinal (cord) injury in trauma patients with suspected spinal injury admitted to the trauma room of the emergency department.
2) To evaluate the used spinal immobilization methods and devices as applied by paramedics according to LPA8.

Methods

DESIGN

Data was collected in an observational, quantitative cross-sectional study. An observational method was an appropriate method because of the necessity of observational data to perform descriptive statistics.[26-27] Moreover, data is collected at the same time for each patient; the design is therefore cross-sectional.[26]

The study was performed at the ED of an academic medical centre in the Netherlands. Data was collected between the 1st of February 2016 and the 15th of April 2016.

POPULATION AND DOMAIN

Because trauma patients indicated for immobilization were necessary, the convenience sample consisted of adult trauma patients (age ≥18) with suspected spinal injury who were admitted to the ED of University Medical Centre Utrecht (UMCU). Patients with the following criteria were excluded: (1) patients transferred from other hospitals, (2) patients admitted to the ED without a trauma team activation signal (patients without this signal are not always admitted by ambulance), (3) patients with pre-existing SCI, and (4) patients who could not understand Dutch.

No sample size was calculated prior to the study whereas this is the first study in evaluating LPA8, and the exact proportion of patients suspected for spinal injury in this setting is unknown. Moreover, only descriptive statistics were performed and there was no need to find a statistical significance.

DATA COLLECTION

The researcher designed a questionnaire to collect data from admitted patients during observations in the trauma room, day and night (Annex 1).

The questionnaire included four aspects. The first aspect included baseline characteristics. These characteristics were taken into account to describe the convenience sample. Baseline characteristic items were age, gender, the mechanism of injury, and the Injury Severity Score (ISS). ISS assesses the severity of the patient's injury by including six individual physical areas (head/neck, face, chest, abdomen, extremities, and external). ISS ranges from 0-75 and is calculated by using the updated Abbreviated Injury Scale method of 1998.[28] A major trauma is defined using a threshold of ISS >15.[29] Information regarding the patient's injury in the patient files was used. Scores with doubts were discussed with the senior researcher in order to find consensus. The second aspect concerned whether admitted patients met the patient profile in LPA7. The four decision criteria in LPA7 were, therefore, included (Table 1). Because decision criterion three is divided into six individual

indicators and decision criterion four is divided into eight individual criteria, a total of 16 individual criteria could be met for every patient. The patient profiles of LPA7 and LPA8 are described in Annex 2. The third aspect includes the used immobilization methods and devices before the initial assessment in the trauma room. Standard procedure before the initial assessment is that devices such as a backboard, stretcher or a vacuum mattress are removed and replaced in a trauma bed. The fourth aspect was the final diagnosis of the patient regarding spinal injury and SCI. This aspect was divided into (1) absence of spinal injury, (2) presence of spinal injury without SCI, or (3) presence of spinal injury with SCI. Spinal injury and SCI were present when the trauma professional described this diagnosis in the patient file, after radiologic tests. When SCI was present, it was mentioned whether the diagnosis concerned sensory and/or motoric failure. Furthermore, the location of the damage (on the cervical, thoracic, or lumbar nerves) was mentioned.

The researcher and trauma nurses working at the ED of UMCU were data collectors (researcher one day a week; trauma nurses six and seven nights a week).

Before data collection started, the researcher trained trauma nurses to collect data and to ask patients for informed consent. Moreover, trauma nurses were updated and reminded of the study by the researcher every two weeks by email.

The researcher reviewed the electronic overview of admitted patients to the ED every week in order to register missed and excluded patients. All patients indicated as “trauma (un)stable” and suspected of having spinal injury were taken into account.

The researcher checked all completed questionnaires for correct inclusion of the patients and reviewed the patient file data for inconsistencies. If the questionnaire data did not match the patient file data, patient file data was considered correct. Moreover, after one month, two trauma nurses were asked whether the questionnaire was clear. Because there was confusion according to questions four and five, the questionnaire was adapted in March 2016 (Annex 3).

DATA ANALYSIS

All collected data was analysed with the following statistical program: Statistical Package for the Social Sciences (SPSS) version 21.

Descriptive statistics were performed in SPSS with the use of frequencies. For the continue variables, a boxplot and histogram were created to check normality of the data. If data was not normally distributed, the median, quartile 1 (Q1), and quartile 3 (Q3) were described. Furthermore, for the categorical variables, the number (n) and frequency (%) were described.

MISSING DATA

In case of missing data on the questionnaires, the patient file was reviewed or the trauma nurse who completed the questionnaire was asked. If data was still missing, no further proceedings were executed. Missing-data imputation could have biased the data in a small sample size.[27]

ETHICAL ISSUES

The Medical Ethics Review Committee (METC) of UMCU stated that the Dutch Medical Research Involving Human Subjects Acts (WMO) does not apply to this study (*protocol number 16/032*).

The researcher or trauma nurse informed the patients and asked them for delayed written informed consent (Annex 4). Delayed informed consent was approved by the METC of UMCU and was necessary because of the impossibility of asking patients for informed consent before data collection started in the trauma room.

Data results

SAMPLE CHARACTERISTICS

A total of 327 patients were indicated as “trauma patient (un)stable” and were suspected of having spinal injury. Of these patients, 133 patients were excluded. The convenience sample of 194 patients remained. Of the convenience sample, 138 patients were missed by the trauma nurses and researcher. For the remaining 56 patients, the questionnaire was completed. Of these 56 patients, 22 patients had no written informed consent. Moreover, three patients with completed questionnaires and informed consent were excluded by the researcher. Thirty-one patients were included in the study and used for data analysis (Figure 1).

Age, ISS, and GCS were *not* normally distributed. The median of age was 47 years (Q1=32, Q3=61) and 19 males were included (61.3%). A major part of the patients (n=25, 80.6%) was admitted after high-energetic traumas. The most common mechanism of injury was a fall (n=15, 48.8%). The median of ISS was 5 (Q1=1, Q3=20) and the median of GCS was 15 (Q1=14, Q3=15) (Table 2).

PATIENT PROFILE IN LPA7 AND DIAGNOSIS OF SPINAL (CORD) INJURY

All patients (n=31, 100%) met ≥1 decision criteria of LPA7 (Table 3). Decision criterion one was met by zero patients (0.0%), decision criterion two was met by twelve patients (38.4%), decision criterion three was met by 27 patients (77.4%), and decision criterion four

was met by thirty patients (96.8%). Of the 16 individual criteria, several patients met ≥2 (n=30, 96.8%), ≥3 (n=25, 80.6%), ≥4 (n=14, 45.3%), ≥5 (n=5, 16.0%), ≥6 (n=2, 6.5%), ≥7 (n=1, 3.2%) and ≥8 (n=0, 0.0%) criteria.

Nine patients (29.0%) were diagnosed with spinal injury (Table 4).Their median ISS was 20 (Q1=7, Q3=25.5) (Table 5). The first criterion was met by zero of the nine patients diagnosed with spinal injury (0%), the second criterion by two of the nine patients diagnosed with spinal injury (22%) and the third and fourth criteria by all nine patients diagnosed with spinal injury (100%).

Moreover, two patients (6.5%) were diagnosed with SCI. Both patients suffered with cervical neurological deficit after their trauma but before they were admitted to the ED (Table 4).

EVALUATION OF IMMOBILIZATION METHODS AND DEVICES

Of the 31 patients, five patients were not immobilized in the pre-hospital phase (16.1%) (Table 6). For the remaining 26 patients, two different positions in which patients were admitted were used: 1) lying (n=20, 64.6%) and 2) half-sitting (n=2, 6.5%). Moreover, for four patients, data of their immobilisation position is missing.

Applied devices were the backboard (n=6, 19.4%), the vacuum mattress (n=13, 41.9%), and the stretcher (n=3, 9.7%). Other devices were head blocks (n=2, 6.5%), C-collar (n=10, 32.3%), and head blocks combined with the C-collar (n=7, 22.6%) (Tables 6-7). For 24 patients (including the five patients not immobilized in the pre-hospital phase), extra immobilization devices were applied at the ED: head blocks (n=9, 29.0%), C-collar (n=2, 6.5%, for both patients a better fitting C-collar), head blocks combined with a C-collar (n=12, 38.7%), and manual therapy (n=1, 3.2%) (Table 7).

Two patients diagnosed with SCI were immobilized during the pre-hospital lying on a backboard with head blocks and a C-collar (for one patient the C-collar was applied on the ED).

Discussion

All 31 patients met ≥1 decision criteria of the patient profile in LPA7. Nine patients were diagnosed with spinal injury and two of them were diagnosed with SCI . All patients diagnosed with spinal injury were immobilized in the pre-hospital phase. Five other patients were not immobilized. To immobilize the patient, two positions were used: lying (n=20, 64.6%) and half-sitting (n=2, 6.5%). Applied devices were: the backboard (n=6, 19.4%), the vacuum mattress (n=13, 41.9%), the stretcher (n=3, 9.7%), head blocks (n=2, 6.5%), C-collar (n=10, 32.3%), and head blocks combined with a C-collar (n=7, 22.6%). For 24 patients,

extra immobilization methods and devices were used at the ED.

If LPA7 was still being used, every patient would have been immobilized in the pre-hospital phase. In the current situation, five patients were not immobilized. None of those five patients were diagnosed with spinal injury. This suggests decision criteria in LPA7 created unnecessary immobilization. For example, the individual criterion: 'accident involving sudden acceleration'. This criterion was met by ten patients in total, but only by two of the patients diagnosed with spinal injury (22.2%).

Included decision criteria of LPA7 in LPA8 require further evaluation. For example, the individual criterion 'inadequate communication' was met by thirteen patients in total but only by two of the patients diagnosed with spinal injury (22.2%). This criterion created, therefore, unnecessary immobilization in this study. Furthermore, results according to the individual criterion 'pain in the spine', are positive (eight of the patients diagnosed with spinal injury met the criterion, 88.9%) but questionable. The questionnaire was completed after immobilisation and time between immobilisation and arrival at the ED is unknown. A 2002 study[30] showed the criterion 'pain in the spine' can be reported after immobilisation and increases with time of immobilisation. Moreover, it is questionable whether the individual criterion 'high-energetic trauma' should have been excluded in LPA8 because it was met by eight of the patients diagnosed with spinal injury (88.9%). On the other hand, this criterion created unnecessary immobilization because 25 patients (80.9%) met the criterion in total.

A discrepancy in used decision criteria and immobilization methods and devices is showed between the pre-hospital phase and the hospital phase. Immobilization methods and devices were applied at the ED for all patients not immobilized in the pre-hospital phase. Moreover, extra immobilization methods and devices were applied for 24 patients at the ED. These findings are in line with a 2015 article[11] in which this discrepancy was mentioned.

The new included immobilization position of half-sitting is used a few times (n=2). Most likely, this is because it is difficult to transfer a patient in a half-sitting position to a trauma bed at the ED.[11] Furthermore, one of the reasons for the revision to LPA8 is to reduce disadvantages for the patient. Although LPA8 describes, there is evidence the backboard and C-collar have disadvantages such as decubitus[10-11,22-23] and positive effects have not been demonstrated[12] , they are often applied (backboard n=6, C-collar n=10). Moreover, head blocks combined with a C-collar are often applied (n=7) in contrast to head blocks alone (n=2). LPA8 describes head blocks as equally effective as head blocks combined with a C-collar, and the C-collar has disadvantages.[22-23] It suggests paramedics do not always apply immobilization methods and devices as pre-scribed in LPA8. This would be in contrast to a 2016 study[31] which showed spinal immobilisation is applied by paramedics according to the applicable protocol in 97.7%. Studies show possible reasons for paramedics to not apply immobilisation methods and devices according to the applicable protocol: (1) paramedics are

not trained properly to use the protocol,[32-33] (2) paramedics need to get used to the new protocol,[33] (3) paramedics have negative attitudes towards the protocol and therefore act on their own experience (they might consider devices such as the backboard and C-collar as effective).[32- 34]

The median of ISS in patients diagnosed with spinal injury was 20 (Q1=7, Q3=25.5). This is remarkably high considering an ISS of 5 (Q1=1, Q3=20) in the total sample. It suggests the injuries of patients diagnosed *with* spinal injury are higher than injuries of patients *without* spinal injury. This was stated as questionable in the introduction.

Moreover, it is questionable whether the sample is representative for the population, considering different findings. The median age was 47 years (Q1=32, Q3=61). The probability of having a spinal injury diagnosis is highest for men around 30 years or for people above 60 years.[35-41] Forty-seven years is not within this range. Nineteen males were included (61.0%). The male/female ratio for the population is however, 2:1.[41] The most common mechanism of injury in the sample was a fall (n=15, 48.8%). For the population, the most common mechanism of injury is a traffic accident (40.0-50.0%).[41] Moreover, an ISS with a median of 5 (Q1=1, Q3=20) suggests a sample with in particular minor injuries.[29]

LIMITATIONS

A major limitation was the impossibility of asking patients with severe injury for informed consent. Almost all patients (n=20, 91.0%) with completed questionnaire but who could not be asked for informed consent had severe injuries or even died. Because data from patients with severe injuries was not used, the number of patients in the sample was strongly reduced, and selection bias occurred. Selection bias could lead to an underestimation of patients diagnosed with spinal injury considering the high ISS in patients diagnosed with spinal injury and the low ISS in patients without spinal injury. On the other hand, in contrast to other medical centres in the area, the ED of UMCU is a trauma centre. Therefore, a possible overestimation is caused because the majority of admitted patients in a trauma centre are suspected of having spinal injury. The results of the study are, therefore, not generalizable to other medical centres in this area.

Despite the fact that trauma nurses were reminded about the study every two weeks, 138 eligible patients were missed. This reduced the number of the sample. It is unknown why they were missed.

Furthermore, baseline characteristics such as age, gender, and mechanism of injury were not representative for the population. Therefore, it is difficult to generalize the results to the entire population.

STRENGHTS

This study is the first in evaluating LPA8. There were no previous studies found that evaluated LPA8.

An observational design was the best design for this study. This design has the highest level of evidence below an experimental design, a case-control study, or a cohort study.[18] Due to the use of trauma patients, it was impossible to perform an experimental design or a case-control study. Moreover, it was not possible to perform a cohort study. Within the research time, a single observation of the patient was feasible to answer the research question.

Furthermore, data collection of the study continued day and night, which ensured no information bias in data collection could have occurred due to the time of inclusion.

More information bias in data collection was reduced as a result of the training prior to the start of data collection and due to the working experience of the trauma nurses. The training focused on correctly completing the questionnaire. Low information bias is supported considering the low exclusion rate of n=3 after all questionnaires were completed.

RECOMMENDATIONS

To prevent confusion between health care professionals, the pre-hospital phase and the hospital phase should use the same decision criteria as well as the same immobilization methods and devices. Results support that decision criteria in LPA7 probably create unnecessary immobilization. Decision criteria in LPA8 require more evaluation because the included sample size was small. Research according to the sensitivity and specificity of included decision criteria is recommended.

Moreover, for clinical practice is recommended to alter or improve used immobilization methods and devices for a better transition between the pre-hospital phase and hospital phase. Pre-hospital methods and devices such as the position of half-sitting should be adapted, or ED's should be better adjusted for methods and devices included in LPA8.

Furthermore, there is need for a study that overcomes the difficulties with obtaining informed consent.

CONCLUSION

Although the patient profile of LPA7 showed all 31 patients met the decision criteria of LPA7, five patients were not immobilized during the pre-hospital phase. Those five patients were, however, not diagnosed with spinal injury. Nine other patients were diagnosed with spinal injury. This supports the strict decision criteria in LPA7 probably create unnecessary immobilization. Decision criteria in LPA8 require further evaluation because of the small included sample size.

According to LPA8, varying immobilization methods and devices are used. Patients were admitted in a lying or half-sitting position on the backboard, vacuum mattress or stretcher. Other applied devices were head blocks and/or a C-collar. Moreover, discrepancies between the pre-hospital phase and hospital phase in used decision criteria and immobilization methods and devices are showed. All patients not immobilized in the pre-hospital phase were immobilized at the ED, and for 24 patients, extra immobilization devices were applied at the ED.

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Table 1, patient profile according to LPA7

1.	2.	3.	4.
Is the trauma patient intubated?	**Glascow Coma Scale <15** (*an assessment of the level of consciousness is < 15, ranged from 3-15*)	**The following indicators are taken into account as any risk on SCI:**	**At least one of these criteria should be met:**
		•The trauma is high-energetic •Each mechanism with a hard blow to the head, neck, torso and pelvis •Lateral forces on the neck and trump •Thrown out of the vehicle (also including scooter, skateboard, cyclist) •Diving in shallow water •Accident involving sudden acceleration/deceleration	•Pain in the spine •Neurological deficit •Intoxication •Facial injury •Distracting pain •Fractured skull •Epileptic seizure •Inadequate communication with the trauma patient

Table 2, baseline characteristics (n=31)

Baseline characteristic	**Frequency (n, %) / Median (Q1, Q3)**	
Age	/ 47 (32, 61)	
Male	19	61.3
ISS*	/ 5 (1,20)	
GCS**	/ 15 (14,15)	
High-energetic trauma	25	80.6
Mechanism of injury		
Fall	15	48.8
Car vs. car	4	12.9
Bicycle vs. car	4	12.9
Car vs. object	4	12.9
Scooter	2	6.5
Other	2	6.5

**Inter Severity Score*
***Glascow Coma Score*

Table 3, patients met criteria in LPA7 (n=31) and patients diagnosed with spinal injury met criteria in LPA7 (n=9)

Criteria of the patient profile according to LPA7	Corresponding patients* (n, %) / Median (Q1,Q3)			Patients diagnosed with spinal injury, met the criteria** (n, %)	
Patients that met ≥1 decision criteria of LPA7***	31	100		9	100.0
1) Patient is intubated	0	0.0		0	0.0
2) GCS** <15**	12	38.4	/15 (14,15)	2	22.2
3) Indicators	27	77.4		9	100.0
1. Trauma is high-energetic	25	80.6		8	88.9
2. Each mechanism with a hard blow to head, neck, torso and pelvis	24	77.4		9	100.0
3. Lateral forces on the neck and trump	10	32.3		4	44.4
4. Thrown out of the vehicle	1	3.2		0	0.0
5. Diving in shallow water	0	0.0		0	0.0
6. Accident involving sudden acceleration/deceleration	10	32.3		2	22.2
4) Criteria	30	96.8		9	100.0
1. Pain in the spine	14	45.3		8	88.9
2. Neurological deficit	1	3.2		1	11.1
3. Intoxication	4	12.9		2	22.2
4. Facial injury	8	25.8		2	22.2

5.	Distracting pain	9	29.0	3	33.3
6.	Fractured skull	1	3.2	0	0.0
7.	Epileptic seizure	1	3.2	0	0.0
8.	Inadequate communication	13	41.9	2	22.2
Patients that met individual criteria					
	≥ 2	30	96.2	9	100.0
	≥ 3	25	80.0	9	100.0
	≥ 4	14	45.3	8	88.9
	≥ 5	5	16	4	44.4
	≥ 6	2	6.5	2	22.2
	≥ 7	1	3.2	1	11.1
	≥ 8	0	0.0	0	0.0

**results in this column are based on 31 patients in total*

***results in this column are based on nine patients in total*

****Landelijke Protocol Ambulancezorg 8*

*****Glascow Coma Scale*

Table 4, final diagnosis according to spinal (cord) injury (n=31)

Final diagnosis		Frequency (n, %)	
Spinal injury present		9	29.0
SCI* present		2	6.5
	Motoric	0	0.0
	Sensory	1	3.2
	Motoric and sensory	1	3.2
	Cervical	2	6.5
	Thoracic	0	0.0
	Lumbar	0	0.0

**Spinal cord injury*

Table 5, baseline characteristics of patients diagnosed with spinal (cord) injury (n=9)

Baseline characteristic	Median (Q1, Q3)/Frequency (N, %)
Male	/ 6, 66.7
High energetic trauma	/ 8, 88.0
Age	51 (31.5,65)
ISS*	20 (7,25.5)
GCS**	15 (14.5,15)
Mechanism of injury	
Fall	/6 66.7
Care vs. object	/2 22.1
Other	/1 11.2

**Inter Severity Score*

***Glascow Coma Score*

Table 6, applied immobilization methods and devices; pre-hospital phase (n=31)

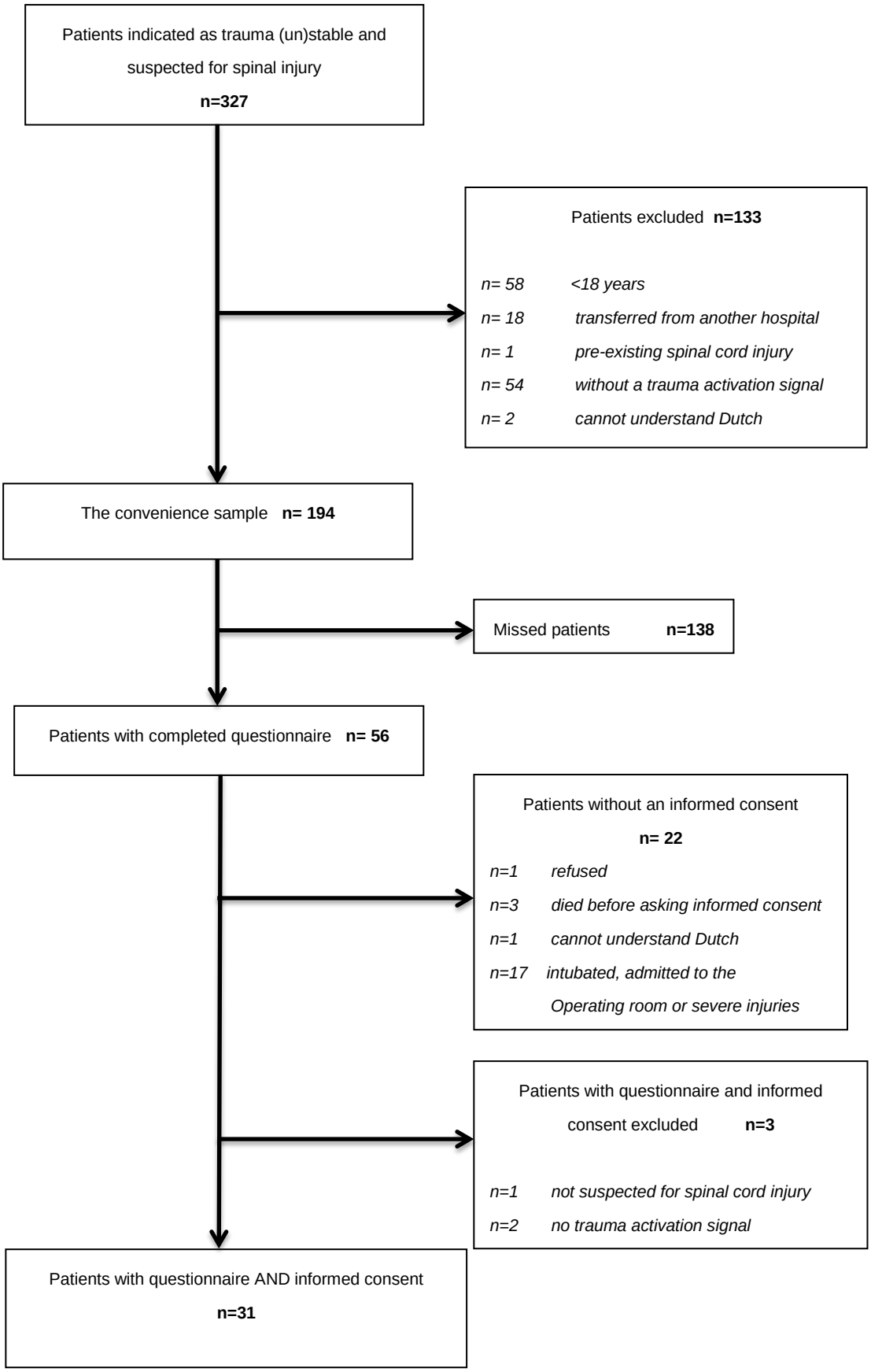
Method	Device 1	Device 2	Frequency (n, %)	
1) Lying flat				
	- backboard		1	3.2
		+head blocks	1	3.2
		+head blocks + c-collar	3	9.7
	- vacuum mattress		4	12.9
		+c-collar	7	22.6
		+head blocks + c-collar	2	6.5

	-stretcher	+head blocks	1	3.2
		+head blocks + c-collar	1	3.2
2)	Half-sitting			
	-vacuum mattress		1	3.2
	-vacuum mattress	+c-collar	1	3.2
3)	Lying/sitting unknown			
	- vacuum mattress	+ c-collar	2	6.5
	- backboard	+head blocks + c-collar	1	3.2
	- stretcher		1	3.2
4)	None		5	16.1

Table 7, applied immobilization devices in total; pre-hospital phase en hospital-phase (n=31)

Used immobilization device		**Frequency (n, %)**	
Pre-hospital phase			
1)	Vacuum mattress	13	41.9
2)	Backboard	6	19.4
3)	Stretcher	3	9.7
4)	C-collar	10	32.3
5)	Head blocks	2	6.5
6)	C-collar and head blocks	7	22.6
Hospital phase (ED)			
1)	None	7	22.9
2)	Head blocks	9	29.0
3)	C-collar	2	6.5
4)	Head blocks and C-collar	12	38.7
5)	Manual immobilization	1	3.2

Figure 1, inclusion scheme



ANNEX 1

Datum: ____ / ____ / ____

Vragenlijst immobilisatie trauma patiënten op de SEH

Deze vragenlijst wordt ingevuld bij binnengebrachte patiënt **NA** een traumasein waarbij er risico is op wervelkolomletsel

Patiënten sticker

Voorbeeld: kruis aan wat van toepassing is voor de patiënt:

Geslacht: ☒ Man

☐ Vrouw

1. Demografische data

1.1 Geslacht	☐ Man ☐ Vrouw ☐ Onbekend
1.2 Leeftijd **Let op:** *vragenlijst hoeft niet verder worden ingevuld indien patiënt jonger is dan 18 jaar.*	… jaar

2. Trauma

2.1 In welke klasse valt het trauma van de patiënt?	☐ Hoogenergetisch trauma ☐ Laag-energetisch trauma

3. Indicatoren immobilisatie

Is er sprake van deze indicatoren **Let op:** *er kunnen ook meerdere indicatoren aangekruist worden*	☐ Glascow Coma Score <15 ☐ Elk mechanisme met een harde klap op het hoofd, nek, romp en bekken ☐ Zijwaartse krachten op nek en romp ☐ Geslingerd uit c.q. van voertuig ☐ Duiken in ondiep water ☐ Ongeval met plotselinge acceleratie/deceleratie
Wordt er ook voldaan aan deze criteria? **Let op:** *er kunnen meerdere criteria aangekruist worden*	☐ Pijn in de wervelkolom ☐ Focale neurologische uitval ☐ Intoxicatie ☐ Aangezichtsletsel ☐ 'Afleidende' pijn en/of verdenking extremiteitsletsel ☐ Verdenking schedelbasisfractuur ☐ Epileptisch insult ☐ Inadequate communicatie met de patiënt

4. Wervelkolom immobilisatie

4.1 Wervelkolom geïmmobiliseerd?	☐ Ja ☐ Nee
4.2 Methoden van immobilisatie **Let op:** *er kunnen meerdere mogelijkheden aangekruist worden*	☐ Backboard ☐ Head blocks ☐ Nekkraag ☐ Schepbrancard ☐ Vacüummatras ☐ Zittend ☐ Liggend ☐ Anders namelijk: _____
4.3 Is er op de SEH nog een vorm van immobilisatie bij de patiënt toegepast? *Bijvoorbeeld: het toevoegen van de nekkraag en/of headblocks*	☐ Ja, namelijk: _____ ☐ Nee

Vanuit het patiëntendossier:

5. Wervelkolom letsel

5.1 Is er sprake van wervelkolomletsel?	☐ Ja, ga naar 5.2 ☐ Nee ☐ Onbekend
5.2 Is er sprake van sensorische – of	☐ Sensorische uitval

motorische uitval?	☐ Motorische uitval
5.3 Waar zit de uitval?	☐ Cervicaal ☐ Thoracaal ☐ Lumbaal

EINDE VRAGENLIJST

Bedankt voor het invullen

ANNEX 2

Figure 2, clinical decision criteria LPA7

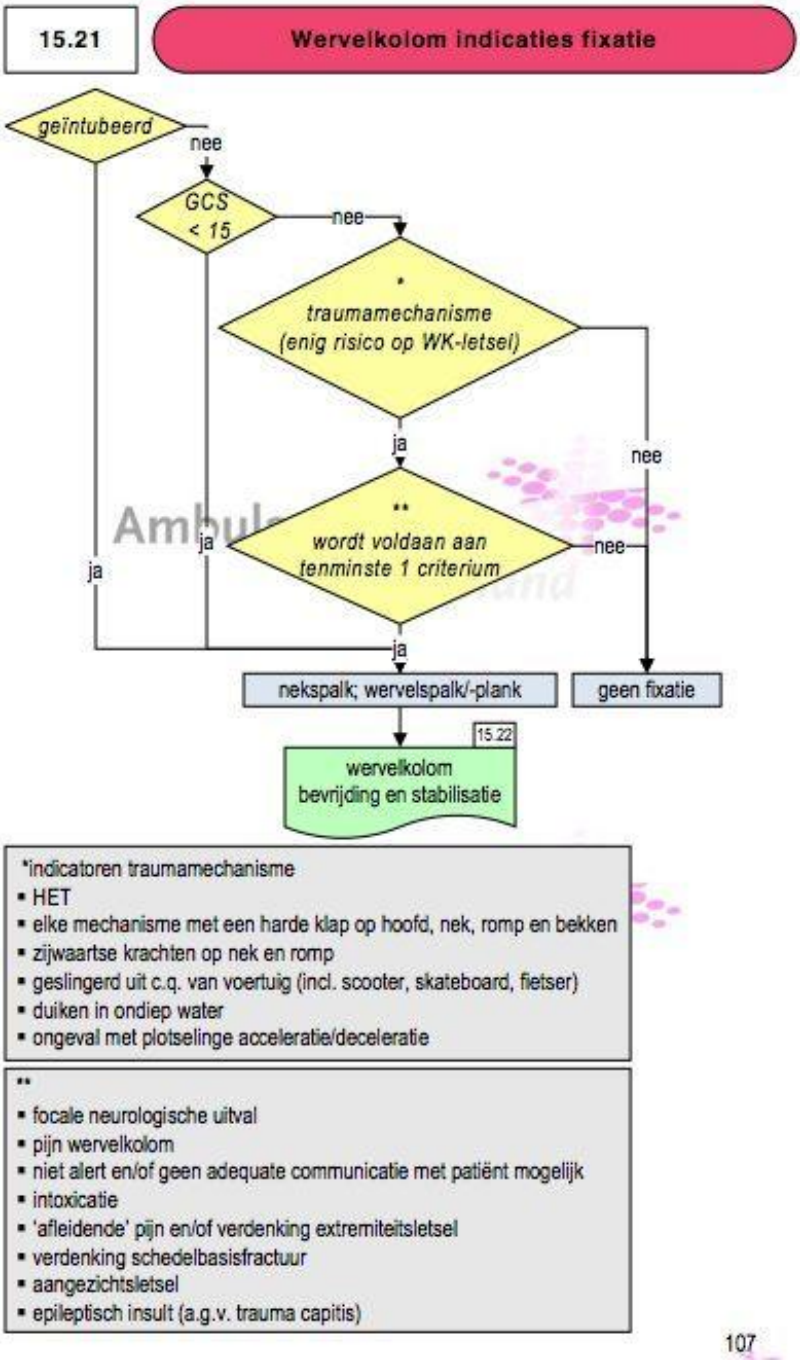
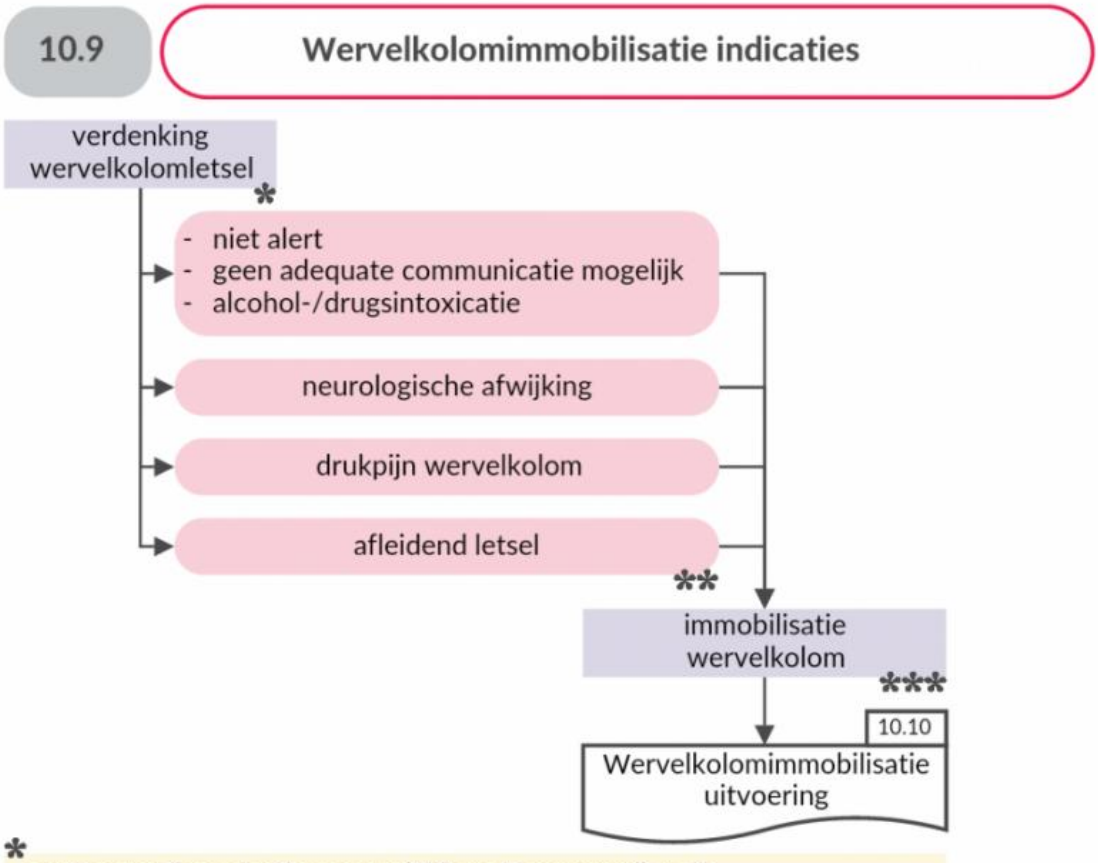


Figure 3, decision criteria LPA8



ANNEX 3

Datum: __/__/__

Vragenlijst immobilisatie trauma patiënten op de SEH

Deze vragenlijst wordt ingevuld bij binnengebrachte patiënt **NA** een traumasein waarbij er risico is op wervelkolomletsel

Patiënten sticker

Voorbeeld: kruis aan wat van toepassing is voor de patiënt:

Geslacht: ☒ Man

☐ Vrouw

2. Demografische data

1.1 Geslacht	☐ Man ☐ Vrouw ☐ Onbekend
1.2 Leeftijd **Let op:** *vragenlijst hoeft niet verder worden ingevuld indien patiënt jonger is dan 18 jaar.*	… jaar

2. Trauma

2.1 In welke klasse valt het trauma van de patiënt?	☐ Hoogenergetisch trauma ☐ Laag-energetisch trauma

5. Indicatoren immobilisatie

Is er sprake van deze indicatoren **Let op:** *er kunnen ook meerdere indicatoren aangekruist worden*	☐ Glascow Coma Score <15 ☐ Elk mechanisme met een harde klap op het hoofd, nek, romp en bekken ☐ Zijwaartse krachten op nek en romp ☐ Geslingerd uit c.q. van voertuig ☐ Duiken in ondiep water ☐ Ongeval met plotselinge acceleratie/deceleratie
Wordt er ook voldaan aan deze criteria? **Let op:** *er kunnen meerdere criteria aangekruist worden*	☐ Pijn in de wervelkolom ☐ Focale neurologische uitval ☐ Intoxicatie ☐ Aangezichtsletsel ☐ 'Afleidende' pijn en/of verdenking extremiteitsletsel ☐ Verdenking schedelbasisfractuur ☐ Epileptisch insult ☐ Inadequate communicatie met de patiënt

6. Wervelkolom immobilisatie

4.1 Wervelkolom geïmmobiliseerd?	☐ Ja ☐ Nee
4.2 Methoden van immobilisatie **bij binnenkomst patiënt** **Let op:** *er kunnen meerdere mogelijkheden aangekruist worden*	☐ Backboard ☐ Head blocks ☐ Nekkraag ☐ Schepbrancard ☐ Vacüummatras ☐ Zittend ☐ Liggend ☐ Anders namelijk: _____
4.3 Is er op de SEH nog een vorm van immobilisatie bij de patiënt toegepast? *Bijvoorbeeld: het toevoegen van de nekkraag en/of headblocks*	☐ Ja, namelijk: _____ ☐ Nee

Vanuit het patiëntendossier:

5. Wervelkolom letsel

5.1 Is er sprake van wervelkolomletsel?	☐ Ja, ga naar 5.2 ☐ Nee ☐ Onbekend
5.2 Is er sprake van sensorische – of	☐ Sensorische uitval

motorische uitval?	☐ Motorische uitval ☐ Geen uitval
5.3 Waar zit de uitval?	☐ Cervicaal ☐ Thoracaal ☐ Lumbaal ☐ Geen uitval

EINDE VRAGENLIJST

Bedankt voor het invullen

ANNEX 4
Informatiebrief

Onderzoek op de spoedeisende hulp van het UMC:
Immobilisatie van rug- en nekwervels bij patiënten die een ongeluk hebben gehad.

Geachte heer/mevrouw,

Wij vragen u vriendelijk om mee te doen aan een medisch-wetenschappelijk onderzoek waarbij de huidige manier van *immobiliseren* bij patiënten die een ongeluk hebben worden bestudeerd.

Immobiliseren betekent dat we ervoor zorgen dat de wervels in de rug en nek niet meer kunnen bewegen. Dat doen we omdat, in geval van gebroken wervels, beweging kan leiden tot verlamming. Gelukkig komt dat niet vaak voor, maar voor de zekerheid zorgen we ervoor dat de wervels in de rug en nek niet kunnen bewegen, totdat duidelijk is dat er geen gebroken wervels zijn.
Om te zorgen dat de wervels niet meer kunnen bewegen, zal de ambulanceverpleegkundige u op een speciale manier vervoeren: bijvoorbeeld met een vacuüm-matras, een harde plank, en vaak ook met een nekkraag. Als u op de afdeling spoedeisende hulp komt, wordt het vacuüm-matras of de harde plank weggehaald, maar vragen we u om stil te blijven liggen. U houdt wel de nekkraag om, totdat we zeker weten dat er geen wervels gebroken zijn. Met dit onderzoek willen we bekijken welke manieren van immobilisatie er bij patiënten worden toegepast en bij wie dit ook daadwerkelijk nodig was.

U beslist zelf of u wilt meedoen. Voordat u de beslissing neemt, is het belangrijk om meer te weten over het onderzoek. Lees deze informatiebrief daarom eerst eens rustig door. Bespreek het met uw partner, vrienden of familie. Hebt u na het lezen van de informatie nog vragen? Dan kunt u terecht bij de onderzoeker. Op bladzijde 3 vindt u haar contactgegevens.

1. Wat is het doel van het onderzoek?
Het doel van dit onderzoek is om te bekijken welke patiënten werden geïmmobiliseerd en wanneer dit ook echt nodig was. Ook zal er worden bekeken welk materiaal er werd gebruikt (harde plank, vacuüm-matras of nekkraag)

2. Welke gegevens worden van u verzameld?
Tijdens uw verblijf op de afdeling spoedeisende hulp zullen wij naast wat basisgegevens (leeftijd, geslacht) ook gegevens over uw gezondheidstoestand verzamelen. Al deze gegevens zijn genoteerd door hulpverleners in uw medische dossier.

3. Hoe wordt het onderzoek uitgevoerd?

Tijdens uw verblijf op de afdeling spoedeisende hulp wordt bekeken welk materiaal werd gebruikt om ervoor te zorgen dat de wervels niet meer kunnen bewegen. De rest van de gegevens die nodig zijn voor dit onderzoek, worden uit het medisch dossier gehaald.

4. Wat wordt er van u verwacht?

Er wordt niets van u verwacht. Er zijn voor u geen beperkingen of veranderingen in de medische en verpleegkundige zorg als u meedoet met dit onderzoek.

5. Wat zijn mogelijke voor- en nadelen van deelname aan dit onderzoek?

U heeft zelf geen voordelen, maar ook geen nadelen bij deelname aan dit onderzoek. Voor de toekomst kan dit onderzoek nuttige gegevens opleveren.

6. Wat gebeurt er als u niet wenst deel te nemen aan dit onderzoek?

U beslist zelf of u meedoet aan het onderzoek. Deelname is vrijwillig. Als u besluit niet mee te doen, hoeft u verder niets te doen. U hoeft niets te tekenen. U hoeft ook niet te zeggen waarom u niet wilt meedoen. Als u patiënt bent, krijgt u gewoon de behandeling die u anders ook zou krijgen. Als u wel meedoet, kunt u zich altijd bedenken en toch stoppen. Ook tijdens het onderzoek. U kunt hierover ten alle tijden contact opnemen met de onderzoeker (zie contactgegevens pag. 3)

7. Wat gebeurt er als het onderzoek is afgelopen?

Het onderzoek heeft geen gevolgen voor u of voor de behandeling en zal stoppen zodra al uw gegevens zijn verzameld.

8. Wat gebeurt er met uw gegevens?

Uw onderzoeksgegevens worden na afloop van het onderzoek nog enige tijd op een veilige plek bewaard. Misschien kunnen we daar later een ander onderzoek mee uitvoeren binnen hetzelfde onderzoeksgebied. Wij zullen u hiervoor dan opnieuw benaderen. Als u niet opnieuw benaderd wilt worden, respecteren wij dat natuurlijk. U kunt uw keuze op het toestemmingsformulier aangeven. U kunt later altijd nog beslissen deze toestemming in te trekken. Na een poos worden alle niet-anonieme onderzoeksgegevens vernietigd.

9. Wilt u verder nog iets weten?

Als u vragen heeft over de gang van zaken rond het onderzoek dan kunt u dit melden aan de onderzoeker of aan uw behandelende arts.

Contactgegevens onderzoeker:
Naam: Wietske Blom-Ham
Email: H.W.Ham@umcutrecht.nl
Telefoon: 088-7566666

Het onderzoeksteam is bereikbaar via tel 088-7566666 (receptie Spoedeisende hulp)

10. Hoe te handelen bij klachten?
Mocht u ontevreden zijn over de gang van zaken bij het onderzoek en een klacht willen indienen dan kunt u contact opnemen met Patiëntenservice. Dit is bereikbaar via tel. 088-755 88 50.

Met vriendelijke groet,
Drs. Wietske Ham

Bijlagen
- Toestemmingsformulier A
Voor volwassenen proefpersonen die zelfstandig beslissingen kunnen nemen (wilsbekwaam zijn)

- Toestemmingsformulier B
Voor de wettelijk vertegenwoordiger/schriftelijk gemachtigde/echtgenoot/partner of levensgezel. Of wanneer deze ontbreken, de ouders van de betrokkene.
Indien ook deze ontbreken, de redelijkerwijs bereikbare meerderjarige kinderen of meerderjarige broers en zussen van de betrokkene

Toestemmingsformulier A

Onderzoek:
Het immobilisatie protocol bij trauma patiënten met kans op gebroken wervels op de spoedeisende hulp..

Toetsingsnummer:
Datum:

Ik heb de informatiebrief gelezen. Ik kon aanvullende vragen stellen. Mijn vragen zijn genoeg beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.

Ik weet dat meedoen helemaal vrijwillig is. Ik weet dat ik op ieder moment kan beslissen om toch niet mee te doen. Daarvoor hoef ik geen reden te geven.

Ik weet dat sommige mensen mijn gegevens kunnen zien. Die mensen staan vermeld in de Algemene brochure.

Ik geef toestemming om mijn gegevens te gebruiken, voor de doelen die in de informatiebrief staan.

Ik geef toestemming om in de toekomst opnieuw gevraagd te worden voor deelname aan nieuw onderzoek. ☐ ja ☐nee

Ik weet dat mijn onderzoeksgegevens na het onderzoek nog enige tijd bewaard worden en daarna worden vernietigd.
Ik vind het goed om aan dit onderzoek mee te doen.

Naam proefpersoon:
Handtekening: Datum : __ / __ / __

Ik verklaar hierbij dat ik deze proefpersoon volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de proefpersoon zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

Naam onderzoeker (of diens vertegenwoordiger):
Handtekening: Datum: __ / __ / __

Aanvullende informatie is gegeven door (indien van toepassing):
Naam:
Functie:
Handtekening: Datum: __ / __ / __

Toestemmingsformulier B

Onderzoek:
Het immobilisatie protocol bij trauma patiënten met kans op gebroken wervels op de spoedeisende hulp.

ToetsingOnline nr en versienummer/datum

Ik ben gevraagd om toestemming te geven voor de volgende persoon, zodat hij meedoet aan dit medisch-wetenschappelijke onderzoek:

Naam proefpersoon: Geboortedatum: __ / __ / __

Ik heb de informatiebrief voor de proefpersoon gelezen. Ik kon aanvullende vragen stellen. Deze vragen zijn naar tevredenheid beantwoord. Ik heb voldoende tijd gehad om te beslissen of deze persoon meedoet.

Ik weet dat meedoen helemaal vrijwillig is. Ik weet dat ik op ieder moment kan beslissen dat deze persoon toch niet meedoet. Daarvoor hoef ik geen reden te geven.

Ik weet dat sommige mensen mijn gegevens kunnen zien. Die mensen staan vermeld in de Algemene brochure.

Ik geef toestemming om de gegevens te gebruiken, voor de doelen die in de informatiebrief staan.

Ik weet dat mijn onderzoeksgegevens na het onderzoek nog enige tijd bewaard worden en daarna worden vernietigd.

Ik vind het goed dat deze persoon meedoet aan dit onderzoek.

Naam wettelijk vertegenwoordiger:

Relatie tot de proefpersoon:

Handtekening: Datum: __ / __ / __

Ik verklaar hierbij dat ik deze persoon/personen volledig heb geïnformeerd over het genoemde onderzoek.

Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de wettelijk vertegenwoordiger zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

Naam onderzoeker (of diens vertegenwoordiger):

Handtekening: Datum: __ / __ / __

Aanvullende informatie is gegeven door (indien van toepassing):

Naam:

Functie:

Handtekening: Datum: __ / __ / __