A stable fracture of the spine, treatment with or without a brace

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21043

Source
Nationaal Trial Register

Brief title
BONO

Health condition

Spinal
Vertebral
Burstfracture
Orthesis

Spinaal
Wervel
Burstfractuur
Orthese/ brace

Sponsors and support

Primary sponsor: Elisabeth-Twee Steden ziekenhuis
Postbus 90151
5000 LC Tilburg
Hilvarenbeekseweg 60
5022 GC Tilburg
Source(s) of monetary or material Support: ZonMw
Experiment Topzorg

Intervention

Outcome measures

Primary outcome

Function score (Oswestry Disability Index) 6 months after trauma.

Secondary outcome

- WHOQoL- Brev

- Short Form-36

- EQ5D

- VAS-pain

- Increase of kyphosis on X-ray (AP and lateral view)

- iMCQ (iMTA Medical Consumption Questionnaire)

- iPCQ (iMTA Productivity Cost Questionnaire)

- WAI (Work Ability Index)

- Length of hospital stay.

Study description

Background summary

Rationale: Thoracolumbar burst fractures are frequently seen in the trauma population, they have a large impact on patient's wellbeing and are a large economic burden to society. Thoracolumbar burst fractures might not need the standard care of brace immobilization for adequate treatment and a functional treatment might lead to same or better functional outcomes. Besides that, with functional outcome length of hospital stay might decrease and it might also be cost effective compared to bracing.

Objective: We aim to study the use of braces for thoracolumbar burstfractures, not only by measuring the functional scores and the effect of the bracing or functional treatment on the increase in kyphosis angle, but also on (health related) quality of life and health economics.

We hypothesize that no treatment is superior over one other by means of function, or pain.

Study design: This project is a randomised controlled trial comparing brace and no brace treatment on function, kyphosis angle, pain, QoL, and costs.

Study population: For the RCT patients between 18 and 65, with a single level thoracolumbar burst fracture will be included. The fracture has to have a kyphosis angle of less than 35 degrees and patient has to be neurologically intact. Patients are excluded when they are overweight (BMI> 35), need multidisciplinary treatment due to multitrauma, or have inadequate knowledge of the Dutch language. Patients included in the brace group will automatically take part in a brace compliance study.

Intervention: One group receives a Thoracolumbar Sacral Orthesis (TLSO) for 6 weeks, the other group receives no TLSO

Main study parameters/endpoints: The primary outcome of this study is the functional score at six months after trauma. Secondary outcomes are pain, kyphosis angle, health related quality of life, healthcare costs and brace compliance.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Literature shows no difference in pain, functional outcome or kyphosis angle, therefore no potential risks are known comparing a brace and a functional treatment. We aim that not using the TLSO results in similar functional outcome, pain and kyphosis angle, and less costs. Patients will be seen at first presentation and during two year follow up at the outpatient clinic at six standard care follow up moments. At these follow up moments a X-ray as part of standard care is made. At or just before each scheduled appointment they will fill in questionnaires taking from 15-45 minutes.

Study objective

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Study design

admission

1-2 weeks

6 weeks

3 months

6 months

1 year

2 years

Intervention

Subjects will wear a TLSO for 6 weeks 24 hours a day or they will not. The TLSO is customised and fitted on admission by the orthopaedic surgeon on call and/ or the supplier. After 6 weeks the subjects in the TLSO group will decrease and stop the use of the orthesis. Depending on their pain complaints patients will be admitted to the hospital and will get adequate pain management following local protocol.

Contacts

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Eligibility criteria

Inclusion criteria

- 18-65 years

- Th10-L4

- AO type A3 or A4 type fractures

- Single level

- Kyphosis < 35 ° at first analysis

- Neurologically intact

- Adequate trauma

Exclusion criteria

- Inadequate knowledge of the Dutch language

- Multitrauma, which asks for multidisciplinary treatment

- Inability to wear a brace due to overweight (BMI> 35)

- Known osteoporosis

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-03-2016
Enrollment:	122
Type:	Anticipated

Ethics review

Positive opinion
Date: 15-03-2016
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45936
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4913
NTR-old	NTR5777
CCMO	NL55565.028.15
OMON	NL-OMON45936

Study results