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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21043

Bron
Nationaal Trial Register

Verkorte titel
BONO

Aandoening

Spinal
Vertebral
Burstfracture
Orthesis

Spinaal
Wervel
Burstfractuur
Orthese/ brace

Ondersteuning

Primaire sponsor: Elisabeth-Twee Steden ziekenhuis
Postbus 90151
5000 LC Tilburg
Hilvarenbeekseweg 60

5022 GC Tilburg
Overige ondersteuning: ZonMw
Experiment Topzorg

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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Onderzoeksopzet

admission

1-2 weeks

6 weeks

3 months

6 months

1 year

2 years

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Elisabeth-Twee Steden ziekenhuis

Wouter Bakker
Hilvarenbeekseweg 60 Postbus 90151

Tilburg 5000 LC
The Netherlands
013-5392942

Wetenschappelijk

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Tilburg 5000 LC
The Netherlands
013-5392942

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 18-65 years

- Th10-L4

- AO type A3 or A4 type fractures

- Single level

- Kyphosis < 35 ° at first analysis

- Neurologically intact

- Adequate trauma

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Inadequate knowledge of the Dutch language

- Multitrauma, which asks for multidisciplinary treatment

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

- Known osteoporosis

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-03-2016
Aantal proefpersonen:	122
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-03-2016

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45936
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten