Efficacy of spinal orthosis in nonsurgical treatment of traumatic thoracolumbar fractures

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The withhold of the use of a spinal orthosis for traumatic spinal fractures will lead to equal pain, radiologic outcome, and quality of life (QoL) in patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON39374

Source
ToetsingOnline

Brief title
Sport-trial

Condition

- Fractures

Synonym
lumbar -and throracic vertebral fractures, spinal column fractures

Research involving
Human

Sponsors and support

Primary sponsor: Rode Kruis Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Nonsurgical, Orthosis, Thoracolumbar fractures

Outcome measures

Primary outcome

No significant reduction of pain by wearing the orthosis, the VAS scale (0-10).

Secondary outcome

Secondary endpoints are: radiological outcome as measured by local and regional

kyphosis and loss off vertebral height on plain lateral and AP X-Rays.

Functional outcome as measured by Qualeffo Questionnaire and the Roland

Morrison Disability Questionnaire, and their dependency on analgesics.

Study description

Background summary

Treatment of thoracolumbar traumatic fractures consists of early mobilization with the aid of a physiotherapist and analgesics, commonly supported by the use of an orthosis. Untill this date there is no scientific evidence that supports the use of an orthosis. Commonly it is assumed that the orthosis diminishes the pain and prevents patients to hyperflex of -extend the spinal column.
The goal of this study is to evaluate that assumption.

Study objective

The withhold of the use of a spinal orthosis for traumatic spinal fractures will lead to equal pain, radiologic outcome, and quality of life (QoL) in patients.

Study design

Prospective multicentre randomized controlled clinical trial. All patients with a traumatic stable thoracolumbar fracture of the spine older than 18 years, whith informed consent, are included. Group 1 is the intervention group and will be wearing an orthosis for 12 weeks, Group 2 serves as a control group and will be treated without an orthosis. Follow up visits are scheduled at 1 week,

6 weeks, 3 months, 6 months and 1 year.
Simultaneously at each visit a VAS, Queleffo and Roland Morrison Questionnaire will be registered. In both groups X-rays will be performed in posterieur-anterior and lateral images, at day 0, 1 week, 6 weeks, 3 months, 6 months and 1 year.
The local sagittal angle and the loss of height will be measured by a radiologist.
Both groups recieve the same follow up, painmedication and fysiotherapy.

Intervention

a spinal orthosis to wear for 12 weeks

Study burden and risks

The follow up appointments take more time to fill in the VAS en the Queleffo questionnaires. The patient will visit the outpatientclinic for one year in 5 visits. In the regular follow up after a thoracolumbar fracture this can involve a shorter follow up period and one less visit.
In literature there is no evidence that treatment with or without an orthosis is associated with any risks

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

18 years and older
Traumatic stable thoracolumbar fracture of the spine (Classification of the fractures according to the AO. Type A1, A2 and A3.1 fractures considered to be stable and suitable to treat non surgical).
Informed consent

Exclusion criteria

none

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-08-2013
Enrollment:	300
Type:	Actual

Medical products/devices used

Generic name:	spinal orthosis;Star- or Hewitt brace
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-02-2013
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	18-06-2013
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL35767.094.11