Orthosis or no orthosis after surgically treated spine fractures

No registrations found.

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

Summary

ID

NL-OMON24770

Source
NTR

Brief title
ORNOT-trial

Health condition

Traumatic thoracolumbar spine fractures

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: Initiator

Intervention

Outcome measures

Primary outcome

Pain scored on the NRS at 6 weeks post-operative.

Secondary outcome

Pain medication used

Quality of life (EQ-5D)

Backpain related function (ODI)

Kyphosis as measured on x-ray

Study description

Background summary

Rationale: There is no evidence in the current literature regarding the additional value of an orthosis after surgically treated thoracolumbar spine fractures.

Objective: To assess whether an orthosis provides additional pain relief compared to no orthosis after posteriorly fixated thoracolumbar spine fractures. Primary outcome is difference in pain at six weeks post-operatively. Secondary objectives are pain at other moments, pain medication used, pain related disability, quality of life, long-term kyphosis.

Study design: Randomized controlled intervention study, non-inferiority trial.

Study population: Dutch speaking patients presented at the VU university medical centre, 18 - 65 years old with a traumatic thoracolumbar spine fracture from Th7 – L4 surgically treated by posterior fixation.

Intervention (if applicable): One group wears an orthosis after surgery for 12 weeks, to use when in vertical position. The other group does not wear an orthosis after surgery.

Main study parameters/endpoints: Main study outcome is the difference in pain noted on the NRS-score at six weeks, ≥ 2 (SD 2,5) change corresponds with a clinically significant change in pain score.

Nature and extent of the burden and risks associated with participation, benefit and group

relatedness: The current guideline for postoperative care regarding dorsal stabilization of spine fractures recommends the use of a post-operative orthosis. While patients generally receive an orthosis for 12 weeks, individual surgeon’s believes sometimes gives reason to deviate from this guideline. This is founded by literature that increasingly questions the use of orthoses in the conservative treatment of spine fractures. With the fracture operatively stabilized, the orthosis mainly provides support of gesture and thereby potentially results in pain relief and confidence for patients. On the other hand some patients report discomfort due to the device and prefer not to use it.

Study objective

No orthosis is not inferior to an orthosis in terms of reported pain after dorsally fixated thoracolumbar fractures.

Study design

Day of discharge

2, 6, 12 weeks postoperative

6, 12 months postoperative

Intervention

One group will receive an orthosis after surgical fixation of thoracolumbar fracture, and the other group will not use an orthosis.

Contacts

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Eligibility criteria

Inclusion criteria

- Age 18 – 65 years

- Traumatic thoracolumbar spine fracture from thoracic 7 – lumbar 4

- AO fracture types A-C

- Undergoing surgical dorsal fixation for fracture

Exclusion criteria

- Inadequate knowledge of Dutch language or to fill in questionnaire

- Complete or partial spinal cord injury (ASIA A to D)

- (Additional) anterior surgical stabilization

- Thoracolumbar fracture of other aetiology than traumatic, e.g. pathologic, infectious

- Not able to walk before fracturing vertebra

- Unable to come to the outpatient clinic (e.g. residing outside the Netherlands)

- Injury Severity Score (ISS) ≥ 16

- Brain injury with Abbreviated Injury Score (AIS) ≥ 4

- Solitary Lumbar 5 fracture

- Inability to wear an orthosis, most probable reasons:

o BMI > 35

o Thoraco-abdominal wounds (through trauma or secondary from surgery) on places at which the orthosis contacts the body so aggravation of pain or chances of infection increase significantly.

o Pre-existing spine deformities (scoliosis or very severe kyphosis/lordosis) which impair the use of the orthosis or aggravate pain.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-11-2016
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-11-2016
Application type:	First submission

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
NTR-new	NL6154
NTR-old	NTR6285
Other	METC : 2016.389

Study results