ORthosis vs No Orthosis after surgically Treated traumatic thoracolumbar fractures

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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...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON47142

Source
ToetsingOnline

Brief title
ORNOT-study

Condition

- Bone and joint therapeutic procedures

Synonym
spine fracture, Thoracolumbar fracture

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Fracture, Orthosis, Surgery, Thoracolumbar

Outcome measures

Primary outcome

Main study parameter is the difference in pain after six weeks noted on the

NRS-score.

Secondary outcome

1. Pain

a. as reported on the NRS scale on each day the brace is worn directly

post-operative (average of 24 hours) and on 2, 6, 12 weeks and 6, 12 months

(average of last week).

b. Pain medication use at the same measuring moments. Rated on three steps;

paracetamol, NSAID*s and opiods, noted as yes/no.

2. Quality of life

a. EQ-5D-5L on day of discharge and at 12 weeks and 6, 12 months

3. Back pain related function

a. ODI at 2, 6, 12 weeks and 6, 12 months.

4. Kyphosis (Cobb-angle)

a. Measured on sagittal CT pre-operative and conventional standing lateral

X-ray at discharge and 6, 12 weeks and 6, 12 months.

5. Increased risk of infections:

a. Wound infection (culture proven or antibiotics given)

b. Decubitus (clinically diagnosed and noted)

c. Pulmonary infections (culture proven or antibiotics given)

d. Urinary tract infections (urinary sample, culture proven or antibiotics

given)

6. Ileus (clinically diagnosed, gastic drainage tube given and noted in chart)

7. Clinically relevant deep venous thrombosis (ultrasound proven and treated)

8. Hospital stay (days)

9. Return to work (weeks/days)

10. Consolidation on long term as seen on X-rays

11. Subjective feeling of:

a. Feeling the need of an orthosis if in the same situation again?

b. Satisfaction with orthosis

c. Subjective feeling of additional value of the orthosis

12. Orthosis compliance

Study description

Background summary

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

Study 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 painmedication used, pain at other moments, pain related disability, quality of life, long-term kyphosis, possible complications, hospital stay, return to work and subjective feeling on benefit or disadvantage from the orthosis.

Study design

Randomized controlled intervention study, non-inferiority trial.

Intervention

Orthosis versus no orthosis.

Study burden and risks

Currently, all patientes receive an orthosis after surgically dorsal stabilization of thoracolumbar fractures, except cases when the treating surgeon has good reasons not to prescribe an orthosis. With subjects being randomized between the use of an orthosis or no orthosis there is no additional risk, there is only one half which does not have to wear an orthosis. We hypothesize there is no difference in postoperative pain and there might be a lower risk of complications related to the orthosis. Participants will receive the same care as patients not included. During hospitalization each day a pain score questionnaire is conducted and on the day of discharge there are two additional questionnaires. Compared to patients not included in the study, included patients will have no additional outpatient appointments but will receive two to three additional questionnaires during the standard outpatient appointments. If the patient is unable to come to the outpatient clinic, an email will be sent to fill in the questionnaires digitally and if there is no response patients will be reminded through telephone or as a last resort the questionnaire will be conducted through telephone. Standard follow-up X-rays are used to measure kyphosis. While at home patients randomized to an orthosis are asked to keep a short diary on their orthosis compliance.

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

- 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
- Diagnosed osteoporosis; using bisphosphonates or diagnosed by DEXA-scan
- Psychiatric history
- 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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-11-2016
Enrollment:	45
Type:	Actual

Medical products/devices used

Generic name:	Hyperextension orthosis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-10-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-09-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT03097081
CCMO	NL58856.029.16