Orthosis or no orthosis after surgically treated spine fractures

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

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

Samenvatting

ID

NL-OMON24770

Bron
NTR

Verkorte titel
ORNOT-trial

Aandoening

Traumatic thoracolumbar spine fractures

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: Initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Day of discharge

2, 6, 12 weeks postoperative

6, 12 months postoperative

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age 18 – 65 years

- Traumatic thoracolumbar spine fracture from thoracic 7 – lumbar 4

- AO fracture types A-C

- Undergoing surgical dorsal fixation for fracture

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	29-11-2016
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	23-11-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6154
NTR-old	NTR6285
Ander register	METC : 2016.389

Resultaten