MAINTAINING SEGMENTAL KYPHOSIS AFTER REMOVAL OF THE INSTRUMENTATION IN PATIENS WITH BALLOON ASSISTED ENDPLATE REDUCTION WITH TRICALCIUM PHOSPHATE BONE CEMENT FOR THORACOLUMBAR BURST FRACTURES.

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The hypothesis of this study is that segmental kyphosis can be maintained after removal of the short-segment pedicle-screw instrumentation in biological young patients with traumatic thoracolumbar burst fractures. In these patients in addition to...

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21920

Bron
NTR

Aandoening

balloon assisted endplate reduction, kyphoplasty, tricalcium phosphate bone cement, TCP, biocompatibility, osteoconductive, osteoinductive

Ondersteuning

Primaire sponsor: Department of Orthopedic Surgery, Orbis Medisch Centrum
Overige ondersteuning: Department of Orthopedic Surgery, Orbis Medisch Centrum

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Standing anteroposterior and lateral roentgenograms pre- and proximally nine months postoperatively and at latest follow-up after removal of the instrumentation will be analysed. The wedge angel, the segmental kyphosis angle and the ratio’s between both the anterior- and the posterior vertebral body height and the central- and posterior vertebral body height are the primay outcomes.

Toelichting onderzoek

Achtergrond van het onderzoek

The objective of our study is to evaluate balloon assisted endplate reduction (BAER) with tricalcium phosphate bone cement (TCP) and short-segment instrumentation for thoracolumbar burst fractures. BAER is a relatively new and promising treatment modality. Combined with pedicle fixation, central elevation of the corpus and reduction of the segmental kyphosis is possible. Theoretically, TCP is an attractive bone filler due to its biocompatibility and osteoconductive properties.
The hypothesis of this study is that because BAER, segmental kyphosis can be maintained in even after removal of the short-segment pedicle-screw instrumentation in biological young patients with traumatic thoracolumbar burst fractures. Furthermore biopsies are taken to evaluate the assumed osteoconductive- and osteoinductive properties of the TCP.

Doel van het onderzoek

The hypothesis of this study is that segmental kyphosis can be maintained after removal of the short-segment pedicle-screw instrumentation in biological young patients with traumatic thoracolumbar burst fractures. In these patients in addition to the short-segment pedicle-screw instrumentation, balloon assisted endplate reduction (BAER) with tricalcium phosphate bone cement (TCP) was performed.

Furthermore biopsies are taken to evaluate the assumed osteoconductive- and osteoinductive properties of the TCP.

Onderzoeksopzet

Standing anteroposterior and lateral roentgenograms pre- and proximally nine months postoperatively and at latest follow-up after removal of the instrumentation will be obtained. The transpedicular biopsies will be taken during the removal of the instrumentation. During

the follow-up after removal of the instrumentation the functional outcomes will be obtained.

Onderzoeksproduct en/of interventie

Removal of the instrumentation after short-segment pedicle-screw instrumentation and balloon assisted endplate reduction with tricalcium phosphate bone cement for patiënts who sustained thoracolumbar burst fractures.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adult patients who sustaine a fresh traumatic thoracolumbar burst fracture (AO-type A3).

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

Neurological deficits, pre-existing spinal deformity, spinal stenosis, osteoporosis (criteria WHO) OR previous spinal surgery.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2011
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL3300
NTR-old	NTR3498
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A