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

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21920

Source

Health condition

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

Sponsors and support

Primary sponsor: Department of Orthopedic Surgery, Orbis Medisch Centrum **Source(s) of monetary or material Support:** Department of Orthopedic Surgery, Orbis Medisch Centrum

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Histological and histochemical analysis of the transpedicular biopsies from the TCP will be performend.

Furthermore Functional outcomes will be determined on the basis of a Visual Analog Pain (VAS) scale, the Short Form-36 score (SF-36) and the Roland Morris Disability Questionnaire score (RDQ) after removal of the instrumentation.

Study description

Background summary

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.

Study objective

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

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osteoinductive properties of the TCP.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

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NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2011
Enrollment:	15
Туре:	Anticipated

Ethics review

Not applicable Application type:

Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3300
NTR-old	NTR3498
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A