PMMA bone cement viscosity in vertebroplasty.

No registrations found.

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

Summary

ID

NL-OMON21242

Source
NTR

Health condition

painful osteoporotic vertebral fractures

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Leids Universitair Medisch Centrum

Intervention

Outcome measures

Primary outcome

Incidence of cement leakage.

Secondary outcome

1. Incidence and clinical relevance of pulmonary and cardiac cement emboli;

2. Incidence of new (adjacent) OVCFs during the first year after PVP;

3. Postoperative pain and health-related quality of Life.

Study description

Background summary

Percutaneous VertebroPlasty (PVP), the percutaneous injection of acrylic bone cement in a fractured vertebral body, is nowadays a generally accepted treatment modality in painful osteoporotic vertebral compression fractures. Methods to reduce complications, like cement leakage and its sequelae such as pulmonary cement emboli and new vertebral fractures, should be explored in order to improve patient safety. Viscosity of bone cement is one crucial parameters which influence the occurrence of cement leakage, the interdigitation of the bone cement with the trabecular bone and the spatial distribution of the cement inside the fractured vertebral body, and hence the clinical outcome after PVP. To what extent, however, is currently unknown and will be determined in this single-blinded, randomized, controlled trial comparing PVP with either a low or a high viscosity bone cement in the treatment of painful osteoporotic vertebral fractures.

Study objective

High viscosity PMMA bone cement reduces the occurrence of cement leakage comprared to low viscosity PMMA bone cement.

Study design

Preoperative, 1, 4, 12, 26, 52 and 104 weeks.

Intervention

Percutaneous vertebroplasty with either high or low viscosity PMMA bone cement.

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Eligibility criteria

Inclusion criteria

All consecutive patients with one or more osteoporotic vertebral compression fractures attending our clinic and considered suitable candidates for PVP will be asked to take participate in this study.

Exclusion criteria

Refusal of participation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2011

Enrollment:	86
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-02-2012
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	NL3138
NTR-old	NTR3282
Other	METC LUMC : P10.055
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A