Prophylactic Reinforcement of Osteoporotic Bone in Elderly.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24464

Source
Nationaal Trial Register

Brief title
PROBE

Health condition

patients with a fresh, low energy, fracture of the hip
heupfracturen
preventie
osteoporose

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: Stichting ST Annadal
MUMC
Maastricht

Intervention

Outcome measures

Primary outcome

Hip fracture.

Secondary outcome

1. Pain (VAS);

2. Efficacy;

3. Radiographic and densitometric;

4. Assessment of bone regeneration after two years.

Study description

Background summary

This study will be the first clinical study concerning profylactic augmentation of the hip in patients with hip fractures in order to prevent an second hipfracture during lifetime.

Study objective

Augmentation of the contralateral hip in patients with a low energy hip fracture over 50Y willdecrease the change of a new hip fracture on the augemented side.

Study design

1. 2 years (investigation);

2. During lifetime (hip fracture).

Intervention

Injection with butyl/methyl methylacrylate, containing iodine in the healthy hip, using a 10 mm hole in the trochanteric region.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patient should have a low energy fracture of the hip at one side;

2. Age over 50;

3. The patient must be surgically and medically accepted for the femoroplasty operation;

4. The patient must have an expected life expectancy of 24 months or greater, as estimated by the physician in charge;

5. The patient must be able to understand sign a study specific informed consent prior to enrolment.

Exclusion criteria

1. The patient may not be estimated unsuitable for femoroplasty e.g. due to previous surgery;

2. Women, who are pregnant or are at risk of getting pregnant during the time of investigation.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2010
Enrollment:	100
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL1641
NTR-old	NTR1739

Register	ID
CCMO	NL26919.068.09
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A