FermaTrial: a study on the treatment of osteoarthritis by means of injections in the hip joint.

No registrations found.

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

Summary

ID

NL-OMON24527

Source
NTR

Brief title
FermaTrial

Health condition

Arthrosis
Hip

Sponsors and support

Primary sponsor: Maatschap Orthopedie, Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Stichting Onderzoek Leeuwarder Orthopedisch chirurgen
Hyaltech provides the hyaluronic acid

Intervention

Outcome measures

Primary outcome

Differences in pain reduction between patients with osteoarthritis of the hip treated with intra-articular injections with Fermathron S (hyaluronic acid) and patients treated with corticosteroids (Depomedrol).

Secondary outcome

1. Differences in function and radiological changes between the group treated with Fermathron S and the group treated with Depomedrol.
2. Safety of Fermathron S in patients with osteoarhritis of the hip.
3. Differences in paracetamol consumption between the group treated with Fermathron S and the group treated with Depomedrol.

Study description

Background summary

Background of the study:
Conservative treatment concerning coxarthosis has been limited to pain medication and physical therapy. Also known are the positive short term effects of intra-articular injections with corticosteriods and hyaluronic acid. However, the long term effects are unknown.

Study design:
Multi centre randomised, blinded and prospective trial consisting of two groups; (I) Hyaluronic acid (Fermathron S) and (II) Corticosteriods (Depomedrol).

Intervention:
Group I will recieve 3 ml hyaluronic acid and 2 ml Lidocaine. Group II will receive 2 ml corticosteriods and 3 ml Lidocaine.

Primary outcome:
To determine differences in pain reduction between patients with osteoarthritis of the hip treated with intra-articular injections with Fermathron S (hyaluronic acid) and patients treated with Depomedrol (corticosteroids) at 6 and 12 months follow-up.

Study objective

The positive short term effects of intra-articular injections with corticosteroids and hyaluronic acid are known. However, the longterm effects are unknown.

Study design

At 6 and 12 months follow-up

Intervention

Group I: 3 ml hyaluronic acid and 2 ml lidocaine
Group II: 2 ml corticosteroids and 3 ml lidocaine

Contacts

Public
Henri Dunantweg 2
8934 AD Leeuwarden
The Netherlands

P.C. Rijk
Leeuwarden 8934 AD
The Netherlands
+(0)58-2867666
Scientific
Henri Dunantweg 2
8934 AD Leeuwarden
The Netherlands

P.C. Rijk
Leeuwarden 8934 AD
The Netherlands
+(0)58-2867666

Eligibility criteria

Inclusion criteria

1. Age 18 years or older
2. Symptomatic coxarthritis
3. Baseline hip pain VAS score of 15 mm or more
4. Signed informed consent

Exclusion criteria

1. Ipsilateral gonarthritis
2. Clinical significant neurologic or vascular disease
3. Previous intra-articular injections in the affected hip
4. Osteonecrosis or osteomyelitis of the affected hip
5. Rheumatoid arthritis or other inflammatory arthrides

6. Previous surgical procedures of the hip
7. Active or suspected infection in or around the hip
8. Limitation to give an intra-articular injection in the affected hip
9. Current treatement with corticisteroids for another disease
10. Serious liver or kidney failure
11. An alcohol or drug addiction
12. Pregnancy or breastfeeding
13. Contraindications to components of Fermatron, Depomedrol or lidocaine

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2014
Enrollment:	188
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 40597
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4228
NTR-old	NTR4373
CCMO	NL44152.099.13
OMON	NL-OMON40597

Study results