

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

Gepubliceerd: 20-03-2014 Laatste bijgewerkt: 15-05-2024

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24527

Bron

NTR

Verkorte titel

FermaTrial

Aandoening

Arthrosis

Hip

Ondersteuning

Primaire sponsor: Maatschap Orthopedie, Medisch Centrum Leeuwarden

Overige ondersteuning: Stichting Onderzoek Leeuwarder Orthopedisch chirurgen
Hyaltech provides the hyaluronic acid

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

Conservative treatment concerning coxarthrosis has been limited to pain medication and physical therapy. Also known are the positive short term effects of intra-articular injections with corticosteroids 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) Corticosteroids (Depomedrol).

Intervention:

Group I will receive 3 ml hyaluronic acid and 2 ml Lidocaine. Group II will receive 2 ml corticosteroids 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.

Doel van het onderzoek

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

Onderzoeksopzet

At 6 and 12 months follow-up

Onderzoeksproduct en/of interventie

Group I: 3 ml hyaluronic acid and 2 ml lidocaine

Group II: 2 ml corticosteroids and 3 ml lidocaine

Contactpersonen

Publiek

Henri Dunantweg 2
8934 AD Leeuwarden
The Netherlands

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

Wetenschappelijk

Henri Dunantweg 2
8934 AD Leeuwarden
The Netherlands

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Ipsilateral gonarthrosis
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 treatment with corticosteroids 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2014
Aantal proefpersonen:	188
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40597

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten