

# Intraarticular treatment of osteoarthritis of the hip: A randomized trial of hyaluronic acid (Fermathron S) vs corticosteroids (Depomedrol).

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Will the hyaluronic acid injections have impact on pain reduction and functional improvement in patients with osteoarthritis of the hip ?

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Joint disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON40597

### Source

ToetsingOnline

### Brief title

FermaTrial: hyaluronic acid vs corticosteroid injections in coxarthrosis

### Condition

- Joint disorders

### Synonym

arthritis of the hip, coxarthrosis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Medisch Centrum Leeuwarden

**Source(s) of monetary or material Support:** Hyaltech, medische hulpmiddelen industrie

## Intervention

**Keyword:** corticosteroid, coxarthrosis, hyaluronan, longterm effects

## Outcome measures

### Primary outcome

The primary purpose of the study is to determine differences in pain reduction between patients with osteoarthritis of the hip treated with intraarticular injections with Fermathron S (hyaluronic acid) and patients treated with Depomedrol (corticosteroids) at 6 and 12 months follow-up.

### Secondary outcome

Secondary parameters

- Differences in function and radiological changes after treatment with Fermathron S will be evaluated by function score forms, questionnaires and x-rays).
- Is Fermathron S a safe product in patients with osteoarthritis of the hip ?
- Is there a difference in paracetamol consumption between the group treated with Fermathon S and the group treated with Depomedrol?

## Study description

### Background summary

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 objective**

Will the hyaluronic acid injections have impact on pain reduction and functional improvement in patients with osteoarthritis of the hip ?

### **Study design**

Multi centre randomised, blinded and prospective trial consisting of two groups; (I) hyaluronic acid (Fermatron 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.

### **Study burden and risks**

X-ray radiation during injection. Injection itself can be experienced as painful, with a very small chance of infection.

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

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

### Exclusion criteria

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 arthritides
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

## Study design

## Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

## Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	188
Type:	Anticipated

## Medical products/devices used

Generic name:	Fermathron S
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	Depomedrol
Generic name:	methylprednisolone
Registration:	Yes - NL intended use

## Ethics review

Approved WMO	
Date:	04-06-2014
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO	
Date:	10-06-2014
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24527

Source: Nationaal Trial Register

Title:

### In other registers

Register	ID
EudraCT	EUCTR2014-001200-22-NL
CCMO	NL44152.099.13
Other	volgt
OMON	NL-OMON24527