Longterm Effects of Intraarticular Hyaluronan vs Corticosteroid in Osteoarthritis of the Hip: A Randomized Controlled Trail

Published: 17-09-2010
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Will the hyaluronan acid injections have impact on painreduction en functional improvement?

Ethical review	Approved WMO
Status	Will not start
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON34660

Source
ToetsingOnline

Brief title
Hyaluronan vs corticosteroid injections in coxarthrosis

Condition

- Joint disorders

Synonym
arthritis of the hip, coxarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Biomet

Intervention

Keyword: corticosteroid, coxarthrosis, hyaluronan, longterm effects

Outcome measures

Primary outcome

The primary purpose of the study is to determine the difference in pain

reduction and functional recovery between the researchgroups.

Secondary outcome

1 and 2 years after randomization, an assessment will be carried out in which

the percentage of patients in each group that recieved a THP is calculated.

In addition, radiological progression during outpatient visits evaluated by

X-ray (every half year) will be assessed.

A possible effect of hyaluronic acid in negafief recent exacerbation of

arthritis is analyzed.

Study description

Background summary

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 hyaluronan acid. However the long term effects are unknown.

Study objective

Will the hyaluronan acid injections have impact on painreduction en functional improvement?

Study design

Multi centre randomised, blinded and prospective trail. consisting three

groups; (I) Hyaluronan acid (HA), (II) Corticosteriods and (III) Control group.

Intervention

Group I will recieve 2ml hyaluronan acids and 3ml lidocaine. Group II will reciece 2ml corticosteriods and 5ml lidocaine. Group III will recieve 5 ml Lidociane. This every 3 months.

Study burden and risks

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

Contacts

Public
Medisch Centrum Leeuwarden

H. Dunantweg 2
8934 AD Leeuwarden
NL
Scientific
Medisch Centrum Leeuwarden

H. Dunantweg 2
8934 AD Leeuwarden
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

above 18 years-old
symptomatic coxarthrosis
signed informed consent

Exclusion criteria

bad health
ipsilateral gonarthritis
clinical significant neurovascular disease
former surgical procedures of the hip
osteonecrosis, osteomyelitis of the hip
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:	300
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Depomedrol

Generic name:	methylprednisolone
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	17-09-2010
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	14-12-2010
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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2010-022106-40-NL
CCMO	NL29912.099.10