Intramuscular corticosteroid injection in hip osteoarthritis: a randomized controlled trial

Published: 21-03-2011
Last updated: 27-04-2024

The objective of this study is to investigate the added effect of an intramuscular (IM) gluteal corticosteroid injection above a placebo IM gluteal injection (saline) on pain symptoms in patients with hip OA, not responding satisfactory to the usual...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON39512

Source
ToetsingOnline

Brief title
HOCI study

Condition

- Joint disorders

Synonym
degenerative hip arthritis, degenerative hip joint disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Reumafonds en Fonds Nuts Ohra

Intervention

Keyword: corticosteroid injection, hip osteoarthritis, treatment

Outcome measures

Primary outcome

The primary study outcome is the severity of pain in rest and pain at walking (NRS 0-10, 0 equals no pain) and WOMAC 3.1 pain subscale (0-100, 0 equals no pain) at 2 weeks follow-up.

Secondary outcome

The secundary outcome measure are

1. the primary outcome measure at the other follow-up moments (4, 6, 12 weeks)

2 WOMAC 3.1 (5-point Likert) function and stiffness subscales. We will normalize the WOMAC function and the WOMAC stiffness subscale both to a 0 to 100 score, where 0 equals no symptoms

3 patients* global assessment (with use of a 7-point Likert scale: 1 = worse than ever to 7 = major improvement)

4 a generic measure for quality of life using Euroqol

5 difference in percentage of responders as defined by OMERACT-OARSI

6 range of motion of the index hip

7 specific adverse effects

Study description

Background summary

Recent international guidelines recommend an intra-articular corticosteroid injection in patients with hip- or kneeOA who have moderate to severe pain not

responding satisfactorily to oral analgesic/anti-inflammatory agents. This is an effective intervention to relieve pain temporarily. However, IA corticosteroid injection in the hip is more painful and more complex than in the knee, because fluoroscopic or ultrasound guidance is necessary. Therefore, in the Netherlands, this intervention is seldom offered to patients. Recent research indicates that a clinically relevant effect might also be present after intramuscular corticosteroid injection, which is less complex than an IA injection.

Study objective

The objective of this study is to investigate the added effect of an intramuscular (IM) gluteal corticosteroid injection above a placebo IM gluteal injection (saline) on pain symptoms in patients with hip OA, not responding satisfactory to the usual pain medication (acetaminophen or NSAID).

Study design

A double blind randomized controlled trial with a two parallel group design and with 12 weeks of follow-up. The randomization will be stratified for setting (primary or secondary care) from which the patient was recruited.

Intervention

An intramuscular gluteal injection with either 40 mg triamcinolone acetate (intervention), or saline water injection (placebo)

Study burden and risks

The participants will be given an intramuscular injection with corticosteroid or placebo. The risks of an intramuscular corticosteroid injection are small. Pain reduction is a possible benefit of this study. Participants are followed up to 12 weeks in which they have to complete a questionnaire on pain and function (VAS,WOMACscore) and on quality of life (EQ-5D) 5 times (baseline, 2, 4, 6, 12 weeks). A physical examination is planned 2 times (baseline, 12 weeks). At baseline an X-ray (Pelvic) is and a blood sample is taken (hs-CRP, ESR).
Participants are requested to keep a daily pain and painmedication dairy up to 2 weeks after injection.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. A diagnosis of hip OA according to the cinical ACR criteria, including radiologic evidence of OA (kellgren-lawrence grading greater or equal than 2)
2. age > 40 years
3. Symptomatic disease for at least 6 months prior to enrolment
4. Persistent pain despite receiving normal pain medication (acetaminophen and/or NSAID) for at least 3 weeks. Pain severity (in rest or on walking) defined as a minimum score of 3 on the Numerical Rating Scale (NRS; 0-10 range)

Exclusion criteria

Local or systemic infection precluding injection, diabetes mellitus, systemic arthritis, allergy to corticosteroid agent, use of oral corticosteroids, coagulopathy, anticoagulant therapy (cumarin type), peptic ulcer, previous intra-articular steroid injection into the index hip in the past 6 months, radiographic signs of osteonecrosis, pregnancy, lactating women, participation in other medical trials and on the waiting list for a hip replacement surgery

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-10-2011
Enrollment:	135
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Kenalog-40
Generic name:	triamcinilon acetate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	sodiumchloride 0.9%
Generic name:	sodiumchloride 0.9%, solution for injection
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	21-03-2011
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-06-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-12-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-12-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-07-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-06-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2011-000213-39-NL
CCMO	NL35353.078.11