Intramuscular corticosteroid injection in hip osteoarthritis: A randomized controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29422

Source
NTR

Brief title
HOCI trial

Health condition

hip
osteoarthritis
corticosteroid injection
intramuscular

Sponsors and support

Primary sponsor: Erasmus MC Rotterdam, Department of General Practice
Source(s) of monetary or material Support: Reumafonds
Fonds NutsOhra

Intervention

Outcome measures

Primary outcome

Pain reduction at 2 weeks follow-up (NRS 0-10, WOMAC pain subscale).

Secondary outcome

1. Pain reduction at 4, 6 and 12 weeks follow-up (NRS, WOMAC pain subscale);

2. Effect on function (WOMAC function subscale), mobility (WOMAC stiffness subscale);

3. Perceived recovery (7-point Likert scale);

4. Response rate according to OARSI/OMERACT criteria;

5. Side effects;

6. Difference between primary and secondary care setting.

Study description

Background summary

Research question:

What is the effect on pain reduction for pain in rest and pain at walking of an intramuscular injection in the upper gluteal region with 40 mg triamcinolone acetate versus injection with saline water in patients with hip osteoarthritis (OA) at short-term follow-up?

Study design:

Prospective, multicenter, double blind, randomized controlled trial.

Study population:

Patients with hip OA presenting in primary (GP) or secondary (orthopedics) care will be eligible for inclusion if they are > 40 years and have persistent pain despite usual oral pain medication.

Intervention:

The patients will be randomized in 2 groups, stratified for setting (primary or secondary). The intervention group receives one intramuscular triamcinolone acetate 40mg intramuscular gluteal injection; the control group receives one saline intramuscular gluteal injection.

Primary outcome measure:

Pain measured with NRS (0-10) and WOMAC pain subscale.

Study objective

What is the effect on pain reduction for pain in rest and pain at walking of an intramuscular injection in the upper gluteal region with 40 mg triamcinolone acetate versus injection with saline water in patients with hip osteoarthritis (OA) at short-term follow-up?

Study design

All outcome measures will be obtained at baseline and 2,4,6 and 12 weeks.

At baseline and at 12 weeks there will also be a physical examination.

Intervention

Intervention group: One injection triamcinolone acetate 40 mg (1ml) intramuscular gluteal region.

Control group: One saline injection (1ml) intramuscular gluteal region.

Contacts

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Eligibility criteria

Inclusion criteria

Patients will be recruited from primary care (general practitioner) or secondary care (outpatient orthopedic clinic). They will be eligible if they:

1. Have a diagnosis of OA of the hip according to clinical ACR criteria, including radiologic signs of OA (Kellgren-Lawrence grading equal or greater than 2);

2. Are older than 40 years;

3. Have symptomatic disease for at least 6 months prior to enrolment;

4. Have persistent pain (score equal or greater than 3, NRS 0-10) despite receiving optimal doses of oral pain medication (acetaminophen and/or NSAID).

Exclusion criteria

Patients will be excluded if they have:

1. Inability to understand Dutch questionnaire;

2. Local or systemic infection;

3. Diabetes mellitus;

4. Systemic arthritis;

5. Allergy to corticosteroid agent;

6. Use of oral corticosteroids;

7. Coagulopathy;

8. Anticoagulant therapy (coumarin type);

9. Peptic ulcer;

10. Previous intra-articular injection into the index hip the past 6 months;

11. Radiologic signs of osteonecrosis;

12. Pregnancy or lactating women;

13. Participation in other medical trials;

14. On the waiting list for total hip arthroplasty.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2011
Enrollment:	135
Type:	Actual

Ethics review

Positive opinion

Date:	04-07-2011
Application type:	First submission

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
NTR-new	NL2825
NTR-old	NTR2966
Other	METC Erasmus MC Rotterdam : 2011-115
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A