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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29422

Bron
NTR

Verkorte titel
HOCI trial

Aandoening

hip
osteoarthritis
corticosteroid injection
intramuscular

Ondersteuning

Primaire sponsor: Erasmus MC Rotterdam, Department of General Practice
Overige ondersteuning: Reumafonds
Fonds NutsOhra

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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?

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2011
Aantal proefpersonen:	135
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	04-07-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2825
NTR-old	NTR2966
Ander register	METC Erasmus MC Rotterdam : 2011-115
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A