Corticosteroid injections in patients with trochanteric pain syndrome: open label randomized clinical trial in general practice

Submission date Recruitment status [X] Prospectively registered 28/04/2006 No longer recruiting [X] Protocol [] Statistical analysis plan Registration date Overall study status 28/04/2006 Completed [X] Results [] Individual participant data Last Edited Condition category 12/09/2011 Musculoskeletal Diseases

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number NTR640

Study information

Scientific Title

Acronym

TIS (Trochanter Injection Study)

Study objectives

Local corticosteroid injections combined with usual care will have a positive effect on experienced recovery and will reduce pain at 3 and 12 months follow up compared to usual care alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Trochanteric pain (trochanteric bursitis, pseudotrochanteric bursitis)

Interventions

- 1. Intervention group: Usual care combined with corticosteroid injections (triamcinolone acetate 40 mg, lidocaine 1%)
- 2. Control group: Usual care

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Triamcinolone acetate, lidocaine

Primary outcome(s)

Experienced recovery (7 points Likert scale) and severity of pain (0-10 visual analogue scale [VAS]) at 3 months follow up.

Key secondary outcome(s))

- 1. Disease specific outcomes of pain and function (WOMAC/HOOS), at 3 and 12 months follow up
- 2. Primary outcomes at 6 weeks and at 6, 9 and 12 months follow-up
- 3. Cost-effectiveness over 12 months of follow-up. Costs will be estimated by medical consumption, and productivity loss (PRODISC).

Completion date

01/05/2007

Eligibility

Key inclusion criteria

Patients aged 18-80 consulting the general practitioner with trochanteric hip pain existing longer then one week, with the following signs:

- 1. Severe local pain by pressure at the trochanter major, but unsure whether the patient recognizes this as the pain he/she consulted for
- 2. Local pain by pressure at the trochanter major, which the patient recognizes as the pain he /she consulted for

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

80 years

Sex

All

Key exclusion criteria

- 1. Patients who dont understand the questionnaires because of inadequate mastering of Dutch language or cognitive disorders
- 2. Patients who presented themselves in the previous year to the GP with the same complaints
- 3. Patients with sensibility disorders due to meralgia paresthetica, patients who previously have undergone hip surgery at the same side and patients with systematic rheumatologic or neurologic disorders

Date of first enrolment

01/05/2006

Date of final enrolment

01/05/2007

Locations

Countries of recruitment

Netherlands

Study participating centre Erasmus Medical Center

Rotterdam Netherlands 3000 DR

Sponsor information

Organisation

Erasmus Medical Center, Department of General Practice (The Netherlands)

ROR

https://ror.org/018906e22

Funder(s)

Funder type

Research organisation

Funder Name

Netherlands Organisation for Health Research and Development (ZonMw)

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2011		Yes	No
Protocol article	protocol	19/09/2007		Yes	No