

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

Submission date 28/04/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/04/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/09/2011	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr S. Bierma-Zeinstra

Contact details
Erasmus Medical Center
Department of General Practice
P.O. Box 1738
Rotterdam
Netherlands
3000 DR
s.bierma-zeinstra@erasmusmc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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).

Overall study start date

01/05/2006

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

80 Years

Sex

Both

Target number of participants

150

Key exclusion criteria

1. Patients who don't 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)

Sponsor details

P.O. Box 1738

Rotterdam

Netherlands

3000 DR

Sponsor type

University/education

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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?
Protocol article	protocol	19/09/2007		Yes	No
Results article	results	01/05/2011		Yes	No