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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

Registration date
28/04/2006

Overall study status
Completed

Last Edited
12/09/2011

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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