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

No registrations found.

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

Summary

ID

NL-OMON20947

Source
NTR

Brief title
TIS = Trochanter Injection Study

Health condition

Trochanteric pain, also known as trochanteric bursitis or pseudotrochanteric bursitis

Sponsors and support

Primary sponsor: Erasmus Medical Center, Department of General Practice
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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).

Study description

Background summary

A remarkable part of patients with hip pain suffer from trochanteric pain syndrome. In this study (cost) effectiveness of local corticosteroid injections will be determined regarding to normal policy in patients with local trochanteric pain syndrome in general practice.

Study objective

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.

Study design

N/A

Intervention

1. Intervention group: Usual care combined with corticosteroid injections (triamcenalonacetaat 40 mg, lidocaine 1%);

2. Control group: Usual care.

Contacts

Public
Erasmus Medical Center, Department of General Practice,
P.O. Box 1738
S. Bierma-Zeinstra
Rotterdam 3000 DR
The Netherlands
+31 (0)10-4087633
Scientific
Erasmus Medical Center, Department of General Practice,
P.O. Box 1738
S. Bierma-Zeinstra
Rotterdam 3000 DR
The Netherlands
+31 (0)10-4087633

Eligibility criteria

Inclusion criteria

Patients aged 18 till 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 thepatient recognizes as the pain he/she consulted for.

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2006
Enrollment:	150
Type:	Actual

Ethics review

Positive opinion

Date:	27-03-2006
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	NL584
NTR-old	NTR640
Other	: N/A
ISRCTN	ISRCTN16994576

Study results

Summary results
N/A