Standardized needle therapy in LE

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20120

Source
Nationaal Trial Register

Health condition

lateral epicondylitis, treatment, injectables, RCT.

Sponsors and support

Primary sponsor: Amphia hospital Breda. OLVG Amsterdam. AMC Amsterdam
Source(s) of monetary or material Support: none.
funds are regarded

Intervention

Outcome measures

Primary outcome

The main study parameters are the changes in pain using a Visual Analog Scale (VAS, 0-100) (Bodian e.a. 2001) 5 months after treatment:

- After provocation test; pain during resisted dorsiflexion of the wrist during full elbow extension

Secondary outcome

Secondary study parameters are the changes in pain using a Visual Analog Scale (VAS, 0-100) compared to baseline 5 months after treatment and after 8 weeks and 1 year after treatment (at rest and after maximun grip strength), functional recovery, Quality adjusted life years and complications

Study description

Study objective

Our hypothesis is that there is no difference in efficacy between perforation and perforation with application of one of the injection fluids. The potential health care efficiency gain consists of more homogeneity in the treatment of LE. Hereby, unnecessary treatments can be avoided, a more universal method of treatment can be established and the quality of the treatment can be improved.

Study design

Assessments will be made before the treatment (baseline), after 8 weeks, 5 months and 1 years after treatment. At the 8 week and 5 months follow-up visit the orthopedic surgeon or trained investigator will perform a physical examination of the elbow and patients will be asked to complete questionnaires at all follow-up moments. After the last follow up moment, the surgeon or investigator will rate any interventions and/or complications

Intervention

The following treatments are investigated:

- Perforation with infiltration of 0.4cc autologous blood; blood is taken by venipuncture and directly injected in the affected tendon

- Perforation with infiltration of 0.4cc dextrose: solution with 4ml of 50% dextrose+ 4ml of 90% saline + 2ml of 1% lidocaine

- Perforation without infiltration all treatments will be performed ultrasound guided and in a standardized and automated way

Contacts

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Eligibility criteria

Inclusion criteria

Patients referred by their GP to the orthopaedic surgeon diagnosed with unilateral Lateral Epicondylitis lasting longer than 6 weeks

• Age between 18 and 65 years

• Unsuccessful conservative treatment

• Able to read and write in Dutch

• Provision of informed consent by patient.

Pain reduction seems dependent on physical factors like high physical job demands. To secure similar group sizes and comparable work-related characteristics at each point in time, block randomization will be used

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

• Prior injection therapy (during this episode of LE), surgery or trauma at the affected elbow.

• Inflammatory diseases (i.e. rheumatoid arthritis, psoriatic arthritis, or reactive arthritis).

• Patients with any other elbow pathology.

• Neck pain or shoulder pain correlated with elbow pain such as C6 radiculopathy or with disability of the arm or other chronic widespread pain syndromes.

• Traumatic onset of LE.

• Bilateral LE (mild cases of LE on the contralateral elbow without functional limitations are allowed).

• Abnormalities on the X-ray.

• Patients with additional pain at the medial epicondyl.

• Allergy for lidocaine

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2015
Enrollment:	165
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-03-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47499
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4446
NTR-old	NTR4569
CCMO	NL46385.101.15
OMON	NL-OMON47499

Study results