Standardized needle therapy in LE

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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,...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20120

Bron
NTR

Aandoening

lateral epicondylitis, treatment, injectables, RCT.

Ondersteuning

Primaire sponsor: Amphia hospital Breda. OLVG Amsterdam. AMC Amsterdam
Overige ondersteuning: none.
funds are regarded

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2015
Aantal proefpersonen:	165
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-03-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47499
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten