Nettoyage epicondylalgie percutaan en fysiotherapie bij patiënten met laterale epicondylalgie

No registrations found.

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

Summary

ID

NL-OMON21604

Source
Nationaal Trial Register

Brief title
PUNT

Health condition

Lateral epicondylalgia

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

The Patient-Rated Tennis Elbow Evaluation (PRTEE) is a patient reported outcome measure (PROM) specifically developed for lateral epicondalgia

Secondary outcome

• Disabilities of the Arm, Shoulder and Hand (DASH) Outcome Measure

• EQ-5D

• Two questions concerning patient satisfaction

• Two questions concerning adherence to physiotherapy in primary care

• Maximal and pain free grip force using a hand dynamometer

• Extensor force of the mm. extensor carpi radialis brevis and longus using a hand held dynamometer

• Active range of motion (ROM) of wrist and elbow

Study description

Background summary

Rationale: Lateral epicondylalgia of the elbow is a common cause for chronic pain in the elbow, where the pain is present for longer than 6 months. Multiple treatment methods for lateral epicondylalgia are described in the literature. In 90% of the cases conservative treatment is successful. But it is unclear what the best treatment modality is in the 10% where a lateral epicondylalgia persists and the previous treatment was without result. There is no current consensus on the treatment that should be considered as standard in these cases. Previous studies have shown that percutaneaous needle tenotomy (PNT) may be an effective minimal invasive method for the treatment of lateral epicondylalgia. To date, studies on PNT have only been performed in cohort design or with low numbers. In the Sint Maartenskliniek PNT is used on indication, but thus without proper scientific support.

Objective: To study the effect of PNT and structured physiotherapy on function and pain of patients with lateral epicondylalgia.

Study design: A single blind randomized controlled trial with two study groups: 1. PNT and structured physio-therapy, and 2. structured physiotherapy only.

Study population: Subjects with lateral epicondylalgia will be selected at the orthopaedic outpatient clinic in our hospital by the orthopaedic surgeon. The patient information will be provided to the patients who are referred to the radiologist for possible percutaneous needle tenotomy.

Intervention: Percutaneaous needle tenotomy (PNT) is a method where multiple micro trauma

are administered in the effected tissue using a needle.

Main study parameters/endpoints: The Patient-Rated Tennis Elbow Evaluation (PRTEE) is a patient reported outcome measure (PROM) specifically developed for lateral epicondalgia. The endpoint of the PRTEE is set at one year post treatment.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: PNT is already a treatment option for these patients in our hospital. The patients included in the study will be seen at several moments: pre-intervention and at 3 months and 1 year post-intervention. The visit at 1 year is not coinciding with standard care. The extra time investment for the patients is 0.5 x 3 = 1.5 hours. Patients participating in this study will not being barred by any additional benefits or risks other than the regular risks for the treatment with PNT. The questionnaires and physical examinations of the upper extremity do not bring any extra burden.

Study objective

We expect that percutaneous needle tenotomy added to structured physiotherapy will have positive effect on function and pain of patients with lateral epicondylalgia

Study design

The patients included in the study will be seen at several moments: pre-intervention and at 3 months and 1 year post-intervention

Intervention

Percutaneous Needle Tenotomy

Contacts

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Eligibility criteria

Inclusion criteria

• Patients with echographic confirmation of lateral epicondylalgia by one or more of the following symptoms: hypervascularisation, deep tendon calcifications, hypoechogenic tendon

• Concordant pain in the region of the extensor tendons with manual compression with the echography transducer

• Pain present for more than 6 months and not reacting to conservative therapy

• Age between 18 and 65 years

Exclusion criteria

• Surgery related to the lateral epicondylalgia

• Systemic joint disease such as rheumatoid arthritis etc.

• Rupture of the extensor tendons

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2016
Enrollment:	66
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-08-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43509
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5844
NTR-old	NTR5999
CCMO	NL56009.048.15
OMON	NL-OMON43509

Study results