Nettoyage epicondylalgie percutaan en fysiotherapie bij patiënten met laterale epicondylalgie

Gepubliceerd: 10-08-2016 Laatst bijgewerkt: 15-05-2024

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

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

Samenvatting

ID

NL-OMON21604

Bron
NTR

Verkorte titel
PUNT

Aandoening

Lateral epicondylalgia

Ondersteuning

Primaire sponsor: Sint Maartenskliniek
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The Patient-Rated Tennis Elbow Evaluation (PRTEE) is a patient reported outcome measure

(PROM) specifically developed for lateral epicondalgia

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Percutaneous Needle Tenotomy

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Surgery related to the lateral epicondylalgia

• Systemic joint disease such as rheumatoid arthritis etc.

• Rupture of the extensor tendons

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2016
Aantal proefpersonen:	66

Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-08-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43509
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten