US-guided Percutaneous needle tenotomy and Physiotherapy in Patients with Lateral Epicondalgia: A single blinded Randomized Controlled Trial

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Primary Objective: To study the effect of PNT and structured physiotherapy on function and pain of patients with lateral epicondylalgia.Secondary Objectives: To study the effect of PNT and structured physiotherapy on quality of life, patient...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON43509

Source
ToetsingOnline

Brief title
PUNT

Condition

- Tendon, ligament and cartilage disorders

Synonym
lateral epicondylalgia, tenniselbow

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

Source(s) of monetary or material Support: Sint Maartenskliniek

Intervention

Keyword: lateral epicondylalgia, needle tenotomy, physiotherapy, RCT

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 - PROM designed to measure physical function and symptoms in patients with any or several musculoskeletal disorders of the upper limb

• EQ-5D - a standardized instrument for use as a measure of health outcome

• Two questions concerning patient satisfaction

• Questionnaire concerning adherence to physiotherapy in primary care

• Maximal and pain free grip force using a hand dynamometer (Lafayette Instrument Co., Europe)

• Extensor force of the mm. extensor carpi radialis brevis and longus using a hand held dynamometer (MicroFET2, Hoggan Health Industries)

• Active range of motion (ROM) of wrist and elbow - measured by the physiotherapist

Study description

Background summary

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. 1,2 Currently, the rationale is that the epicondylalgia is the result of the respective strain of the hand, wrist and elbow. But it can also be initiated by an acute trauma. In some cases the symptoms of the epicondylalgia can be difficult to treat with resulting persistent pain and restrictions in activities in daily life.

Multiple treatment methods for lateral epicondylalgia are described in the literature. 2-8 These methods can be categorized in conservative, minimal invasive and operative treatments. Conservative treatment is often long-term physiotherapy ranging from ten to eighteen months. 3,4 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. 9-11 For this method multiple micro trauma administered in the effected tissue using a needle. The rationale for this is that the subsequent inflammation results in a decrease of the symptoms. PNT can be performed under local anesthetics and is often performed using corticosteroids. However, it has been show that this addition does not lead to better results. 9

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. Our goal is therefore to study in an RCT with appropriate power if PNT, together with structured physiotherapy, is an effective treatment for lateral epicondylalgia.

(see protocol for references)

Study objective

Primary Objective: To study the effect of PNT and structured physiotherapy on function and pain of patients with lateral epicondylalgia.
Secondary Objectives: To study the effect of PNT and structured physiotherapy on quality of life, patient satisfaction, force of hand and fingers and range of motion of wrist and elbow

Study design

A randomized controlled trial with two study groups: 1. PNT and structured physio-therapy, and 2. structured physiotherapy only.
Measurements will be performed up to one year, with PNT therapy and checkup visits and taking place in the Sint Maartenskliniek, Ubbergen.

Intervention

Percutaneous needle tenotomy and physiotherapy

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

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:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	52
Type:	Anticipated

Ethics review

Approved WMO

Date:	18-02-2016
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21604
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL56009.048.15
OMON	NL-OMON21604