US-guided Percutaneous needle tenotomy in Patients with Lateral Elbow Tendinopathy: A multicenter Randomized Controlled Trial

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To study the effect of PNT and structured exercises on function and pain of patients with lateral elbow tendinopathy.

Ethical review	Approved WMO
Status	Completed
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON46011

Source
ToetsingOnline

Brief title
PUNT

Condition

- Tendon, ligament and cartilage disorders

Synonym
lateral elbow tendinopathy, tenniselbow

Research involving
Human

Sponsors and support

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

Intervention

Keyword: lateral elbow tendinopathy, local anaesthesia, needle tenotomy, structured exercise

Outcome measures

Primary outcome

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

Secondary outcome

• Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH) Outcome Measure - a questionnaire 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 patiënt satisfaction

• Questionnaire concerning adherence and possible difficulties with the structured exercise schedule

• Pain measured using the numerical rating scale (NRS)

Study description

Background summary

Lateral Elbow Tendinopathy (LET) 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 tendinopathy is the result of the repetitive strain of the hand, wrist and elbow. However, it can also be initiated by an acute trauma. In some cases the symptoms of the tendinopathy can be difficult to treat with resulting persistent pain and restrictions in activities in daily life.

Multiple treatment methods for LET 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 within 12 months. (9-10) It is however unclear what the best treatment modality is in the 10% where a LET 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 percutaneous needle tenotomy (PNT) may be an effective minimal invasive method for the treatment of LET. (11-13) For this method multiple microtrauma are administered in the affected 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 (LA). Therefore, an effect of PNT can also be driven by effects of injection of the LA through hydrodissection. Injection of an anaesthetic bolus can cause shearing or compression (mechanical effects) between the surface of the common extensor tendon and superficial fat plane.(14) This mechanical action together with neurotoxic and vasoconstrictive effects of the anaesthetics can target the neovessels and nerves, potentially having a beneficial effect on chronic LET. Such effects have been observed in chronic patellar and Achilles tendinopathy, but thus far are not evaluated in LET.

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 sufficiënt power if PNT under local anaesthetics, together with structured exercise, is an effective treatment for LET when contrasted with local anaesthetics, together with structured exercise, and structured exercise alone.

(see protocol for references)

Study objective

To study the effect of PNT and structured exercises on function and pain of patients with lateral elbow tendinopathy.

Study design

A multicenter, randomized controlled trial with three study groups: 1. PNT and structured exercise, 2. local anaesthetics (hydrodissection) and structured exercise, and 3. structured exercise only.

Measurements will be performed at baseline and at 3 months after intervention in the participating medical centers that recruited the patiënt.

Intervention

Percutaneous needle tenotomy, local anaesthetics and structured exercise

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 or local anaesthetics. The questionnaires of the upper extremity do not bring any extra burden, except an extra time investment of 2x 30 minutes.

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

• Age between 18 and 65 years

• Pain in the elbow present for more than 12 months, unresponsive to conservative treatment
• Sonographically proven tendinopathy (hypervascularisation, deep tendon calcifications, hypoechogenic tendon, erosive cortex)
• Concordant pain during compression with a US Probe in the region of the extensor tendons
• Is able to give informed consent
• Is instructable to follow the exercises

Exclusion criteria

• Surgery related to the lateral elbow tendinopathy, including Needle Aspiration of Calcific Deposits (NACD)
• Systemic joint disease such as rheumatoid arthritis etc.
• Rupture or clefts >1cm of the extensor tendons
• Detachment of extensor tendons or tears in collateral ligament
• Contraindication for lidocaïne in accordance to the SPC
• Pregnancy
• Use of anti-inflammatory drugs, such as NSAIDs, steroids, methotrexate, anti-TNF, azathioprine
• Use of anticoagulant drugs which is bridged with acetylsalicylate acid
• Physical, emotional or neurological conditions that would compromise the patient*s compliance with postoperative rehabilitation protocol follow-up (e.g.: drug or alcohol abuse, serious mental illness, or general neurological conditions such as Parkinson, Multiple Sclerosis, etc.)

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: Completed

Start date (anticipated):	28-11-2018
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	lidocaine HCL
Generic name:	lidocainehydrochloride
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	09-08-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-08-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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: 24205
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2018-002822-22-NL
CCMO	NL66032.091.18

Study results

Date completed:	30-03-2022
Results posted:	05-12-2024
Actual enrolment:	15

First publication
01-01-1900