The effect of US-guided percutaneous needle tenotomy and physiotherapy in lateral elbow tendinopathy (tennis elbow)

No registrations found.

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

Summary

ID

NL-OMON24205

Source
Nationaal Trial Register

Brief title
PUNT

Health condition

Lateral Elbow Tendinopathy (tennis elbow)

Lateral Elbow Tendinopathy (tenniselleboog)

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

The score on Patient-Rated Tennis Elbow Evaluation (PRTEE) at baseline and three months post treatment.

Secondary outcome

• Pain measured using the numerical rating scale (NRS)

• 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.

• Questionnaire concerning adherence to physiotherapy in primary care

• Two questions concerning patient satisfaction

Study description

Background summary

Rationale: Lateral Elbow Tendinopathy (LET) is a common cause for chronic pain in the elbow, where
the pain is present for longer than 6 months. Multiple treatment methods for LET are described in
the literature. In 90% of the cases conservative treatment is successful. It is however unclear what
the best treatment modality is in the 10% where a LET persists and was unresponsive to the previous
treatment. 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. 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 on function and pain of patients with LET.

Study design: A multicenter randomized controlled trial with three study groups: 1. PNT and structured physiotherapy, 2. local anesthetics (LA) and structured physiotherapy and 3.

structured
physiotherapy only.

Study population: Subjects with LET 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 PNT or LA.

Intervention: PNT is a method where multiple microtrauma are administered in the affected tissue
using a needle following LA. Hence, LA might have an effect due to hydrodissection. The injection of
the anesthetic bolus between surface of the tendon and fat plane can have a beneficial effect on the
neovessels and nerves through mechanical action, in combination with neurotoxicity and vasoconstriction.

Main study parameters/endpoints: The Patient-Rated Tennis Elbow Evaluation (PRTEE) is a patient
reported outcome measure (PROM) specifically developed for LET. The endpoint of the PRTEE is set
at 3 months 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 pre-intervention and at 3 months. At 3 months post-intervention the patients will be asked to complete the questionnaires and return them to the clinic.
The extra time investment for the patients is 0.5 x 2 = 1 hour. 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 and LA. The questionnaires and physical examinations of the upper extremity do not bring
any extra burden.

Study design

Baseline and 3 months post treatment

Intervention

- Percutaneous needle treatment

- Local anaesthesia

- Physiotherapy

Contacts

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Eligibility criteria

Inclusion criteria

• Age between 18 and 65 years

• Pain in the elbow present for more than 12 months, unresponsive to conservative therapy

• 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

Exclusion criteria

• Surgery related to the lateral elbow tendinopathy

• Systemic joint disease such as rheumatoid arthritis etc.

• Rupture of the extensor tendons

• Pregnancy

• Contraindication for bupivacaïne

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2018
Enrollment:	66
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-05-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46011
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6432
NTR-old	NTR7223
CCMO	NL66032.091.18
OMON	NL-OMON46011

Study results