

# "Tenease" - a new treatment for tennis elbow

<b>Submission date</b> 26/01/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 08/03/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/01/2019	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Tennis elbow is a painful condition of the elbow that is both common and debilitating. We are investigating a new type of treatment called Tenease. It is a small device that straps onto the elbow and is worn for a short period each day.

### Who can participate?

People over 18 years old who have a new diagnosis of tennis elbow from their GP.

### What does the study involve?

Participants will be randomly allocated to receive either the standard treatment for tennis elbow (painkillers etc) for 6 weeks, or the standard treatment and a Tenease unit. We can then see if there is any difference between the two groups. We will be following patients for a year to see if any differences last.

### What are the possible benefits and risks of participating?

Participants may experience an improvement in their symptoms.

### Where is the study run from?

Royal Devon & Exeter NHS Foundation Trust (UK)

### When is the study starting and how long is it expected to run for?

February 2012 to February 2014

### Who is funding the study?

Royal Devon & Exeter NHS Foundation Trust (UK)

### Who is the main contact?

Mr Andrew Toms

## Contact information

### Type(s)

Scientific

**Contact name**

Mr Andrew Toms

**Contact details**

Royal Devon & Exeter NHS Foundation NHS Trust  
Barrack Road  
Exeter  
United Kingdom  
EX2 5DW

## **Additional identifiers**

**Protocol serial number**

N/A

## **Study information**

**Scientific Title**

"Tenease" - can localised vibration therapy reduce the pain associated with tennis elbow? A pilot randomised controlled trial

**Study objectives**

Null hypothesis:

The Tenease therapy will provide no extra benefit in the treatment of Lateral Epicondyle Tendonopathy (LET) that routine treatment from the General Practitioner alone. Analysis of the pilot study data will allow us to perform a power calculation for a larger randomised controlled study.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee South West - Exeter, 26 September 2011 ref: 11/SW/0190

**Study design**

Pilot single centre randomised study

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Lateral epicondyle tendonopathy

**Interventions**

Tenease (vibration therapy unit) and conventional Tennis Elbow treatment (analgesia and activity modification) versus. conventional treatment alone.

Duration of treatment 6 weeks, follow up 12 months.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Average intensity of pain in the elbow over 24 hours, at 6 weeks from commencement of treatment

**Key secondary outcome(s)**

1. Grip strength
2. Pain
3. Limitation of function
4. Global assessment of change
5. Days of sick leave
6. Overall health status

**Completion date**

01/02/2014

**Eligibility****Key inclusion criteria**

1. Male and female
2. Over 18 years old
3. Consulting their GP with a first diagnosis of lateral epicondyle tendonopathy
4. Diagnosis will be made clinically by the GP
5. Diagnosed with the following symptoms:
  - 5.1. Pain on the lateral elbow that radiates down the forearm
  - 5.2. Point tenderness over the origin of the extensor muscles or at its close proximity (within 2.5 cm)
  - 5.3. Pain on resisted extension of the wrist
  - 5.4. Pain on resisted extension of the middle finger
6. Patients must speak English, be willing to take part and able to consent to the trial

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Concomitant inflammatory arthritides
2. Structural abnormality of the elbow
3. Unable to comprehend the instructions of the Tenease unit
4. Unable to apply the unit correctly

**Date of first enrolment**

01/02/2012

**Date of final enrolment**

01/02/2014

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

Royal Devon & Exeter NHS Foundation NHS Trust

Exeter

United Kingdom

EX2 5DW

**Sponsor information****Organisation**

Royal Devon & Exeter NHS Foundation Trust (UK)

**ROR**

<https://ror.org/03085z545>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/09/2018	21/01/2019	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes