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"Tenease" - a new treatment for tennis elbow

Submission date 26/01/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/03/2012	**Overall study status** Completed	
Last Edited 21/01/2019	**Condition category** Musculoskeletal Diseases	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)

GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

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

Overall study start date
01/02/2012

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

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
England

United Kingdom

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)

Sponsor details
Barrack Road
Exeter
England
United Kingdom
EX2 5DW

Sponsor type
Hospital/treatment centre

Website
http://www.rdehospital.nhs.uk/

ROR
https://ror.org/03085z545

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Devon & Exeter NHS Foundation Trust (UK) ref: AT/28/7/11

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	01/09/2018	21/01/2019	Yes	No