

Tennis elbow platelet-rich plasma injection study

Submission date 15/07/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/07/2015	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/01/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Tennis elbow is a common condition that causes lateral elbow pain. It is associated with repetitive activity at work and play and is thought to be caused by micro-tears in the tendons of the elbow. Although many cases resolve over a period of 3 months, either with or without non-surgical treatments such as rest, exercises and bracing, other treatments may be necessary such as corticosteroid injections or surgery. In an autologous blood injection, blood is taken from the patient and re-injected around the affected tendon. Either whole blood can be injected, or a fragment known as platelet-rich plasma (PRP) can be separated from the red blood cells and injected. PRP contains a high level of growth factors which are thought to stimulate the healing process. The primary aim of this study is to assess feasibility and guide the planning of a large multi-centre study to investigate both the clinical and cost effectiveness of PRP as a treatment for tennis elbow. Three treatment options will be investigated; an injection of either whole blood, PRP or saline using a technique called needle barbotage that disrupts tendon fibres and promotes the healing process.

Who can participate?

Patients aged between 18-65 attending Robert Jones and Agnes Hunt Orthopaedic Hospital with symptoms of Tennis Elbow.

What does the study involve?

Participants are allocated to one of three groups at random. Those in group 1 are given a whole blood injection. Those in group 2 are given PRP. Those in group 3 are given saline. Assessments of pain and elbow function are carried out at 6 weeks, 12 weeks, 6 months and 1 year.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

March 2015 to April 2016

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

Robert Jones & Agnes Hunt Orthopaedic & District Hospital, Oswestry (UK)

Who is funding the study?

The British Elbow & Shoulder Society (BESS), Lavender Medical and The Orthopaedic Institute Limited.

Who is the main contact?

Dr Johanna Wales

Contact information

Type(s)

Public

Contact name

Dr Johanna Wales

Contact details

Robert Jones & Agnes Hunt Orthopaedic & District Hospital

ARC Building

Twmpath Lane

Oswestry

United Kingdom

SY10 7AG

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

17180

Study information

Scientific Title

A pilot study of platelet-rich plasma (PRP) versus autologous whole blood versus saline in the treatment of resistant tennis elbow

Acronym

TEPIS

Study objectives

The primary aim of this study is to assess feasibility and guide the planning of a large multi-centre study to investigate both the clinical and cost effectiveness of platelet-rich plasma (PRP) as a treatment for tennis elbow. Three treatment options will be investigated; an injection of

either whole blood, PRP or saline using a technique called needle barbotage that disrupts tendon fibres and promotes the healing process. Patients will be allocated to one of the treatment groups at random.

Ethics approval required

Old ethics approval format

Ethics approval(s)

First MREC approval date 22/08/2014, ref: 14/WM/1063;

Study design

Randomized; Interventional; Design type: Treatment

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Topic: Musculoskeletal disorders; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions

Injection of either whole blood, platelet-rich plasma or saline using a technique called needle barbotage that disrupts tendon fibres and promotes the healing process
Follow Up Length: 12 month(s)

Intervention Type

Biological/Vaccine

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Platelet-rich plasma injection

Primary outcome measure

Patient rated tennis elbow evaluation (PRTEE); Timepoint(s): 12 weeks post-injection

Secondary outcome measures

1. Adverse events; Timepoint(s): peri-procedural, 6 weeks, 12 weeks, 6 months and 12 months
2. Disabilities of the arm, shoulder and hand (DASH) questionnaire; Timepoint(s): 6 weeks, 12 weeks, 6 months and 12 months
3. EQ-5D; Timepoint(s): 6 weeks, 12 weeks, 6 months and 12 months
4. Health economic data (resource usage); Timepoint(s): 6 weeks, 12 weeks, 6 months and 12 months; 5. Loss to follow-up and withdrawal rates; Timepoint(s): 12 months
6. Mayo elbow performance indicator (MEPI); Timepoint(s): 6 weeks, 12 weeks, 6 months and 12 months; Recruitment rate; Timepoint(s): 12 months
7. Visual analogue pain score; Timepoint(s): 6 weeks, 12 weeks, 6 months and 12 months

Overall study start date

09/03/2015

Completion date

17/03/2021

Reason abandoned (if study stopped)

Objectives no longer viable

Eligibility

Key inclusion criteria

1. Established lateral epicondyle tendinopathy with a minimum symptom duration of 3 months
2. Aged 18 years or above and below 65 years
3. Willing to avoid the use of topical and oral nonsteroidal anti-inflammatory drugs for a period of 6 weeks following injection
4. Has completed the study physiotherapy program for a minimum period of 6 weeks with no improvement in symptoms

Target Gender: Male & Female; Upper Age Limit 65 years ; Lower Age Limit 18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

Planned Sample Size: 30; UK Sample Size: 30

Total final enrolment

29

Key exclusion criteria

1. Bilateral tennis elbow
2. Currently taking part in any interventional study that may impact upon study outcomes.
3. A concomitant injury that may impact on the ability to complete outcome assessments
4. Previous surgical intervention of the tendinopathy
5. Inflammatory disease, or chronic widespread pain syndrome
6. Requires regular use of anti-inflammatory medication for complaints other than Tennis Elbow
7. Known platelet dysfunction or thrombocytopaenia, or haemodynamic instability
8. Malignancy
9. Unable or unwilling to complete the 12 month follow-up assessments
10. Unable to communicate fluently in English or an inability to respond to validated questionnaires written in the English language
11. Platelet count <105/microlitre
12. Corticosteroid injection at the treatment site within the last 4 weeks, or systemic use of corticosteroids within the last 2 weeks. Anti-coagulation therapy within 5 days before treatment
13. Treatment with Non-steroidal anti-inflammatory drugs within 1 week prior to treatment
14. Septicaemia or fever

Date of first enrolment

09/03/2015

Date of final enrolment

01/04/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Robert Jones & Agnes Hunt Orthopaedic & District Hospital

ARC Building

Twmpath Lane

Oswestry

United Kingdom

SY10 7AG

Sponsor information

Organisation

The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust

Sponsor details

The Robert Jones and Agnes Hunt Orthopaedic Hospital
Twmpath Lane
Oswestry
England
United Kingdom
SY10 7AG

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/030mbcp39>

Funder(s)**Funder type**

Government

Funder Name

British Elbow & Shoulder Society (BESS)

Funder Name

Lavender Medical

Funder Name

The Orthopaedic Institute Limited

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?
HRA research summary			26/07/2023	No	No