# Tennis elbow platelet-rich plasma injection study

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

#### 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

Protocol serial number

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 multicentre 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

#### Study type(s)

Treatment

#### 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

#### Phase

Not Applicable

## Drug/device/biological/vaccine name(s)

Platelet-rich plasma injection

## Primary outcome(s)

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

## Key secondary outcome(s))

- 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 (resourse 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

## 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Upper age limit

65 years

#### Sex

All

#### 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

United Kingdom

England

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

#### **ROR**

https://ror.org/030mbcp39

# Funder(s)

## Funder type

Government

#### **Funder Name**

British Elbow & Shoulder Society (BESS)

#### **Funder Name**

Lavender Medical

#### **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?
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes