ISRCTN12951626 https://doi.org/10.1186/ISRCTN12951626

Tennis elbow platelet-rich plasma injection study

Submission date
15/07/2015

Recruitment status
No longer recruiting

Registration date
16/07/2015

Overall study status
Stopped

Last Edited
15/01/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 (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

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