



Health Research Authority

West Midlands - Black Country Research Ethics Committee

Royal Standard Place
Nottingham
NG1 6FS

15 February 2016

Dr Joanne O'Beirne-Elliman
Warwick Clinical Trials Unit
Warwick Medical School
The University of Warwick
Coventry
CV4 7AL

Dear Dr O'Beirne-Elliman

Study title:	Achilles Tendinopathy Management (ATM): A multi-centre placebo controlled randomised controlled trial comparing Platelet Rich Plasma (PRP) to placebo (imitation) injection in adults with Achilles tendon pain
REC reference:	15/WM/0359
Amendment number:	1
Amendment date:	11 January 2016
IRAS project ID:	187315

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Discussion

The Sub-Committee commented on the addition of anticoagulant and note that this is not mentioned in Participant Information Sheet along with the risks (if any). The Sub-Committee requested that this be clarified and amended within the document.

The applicant submitted an updated Participant Information Sheet to reflect the comments of the Sub-Committee.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper		12 January 2016
GP/consultant information sheets or letters [GP Notification letter]	2.0	21 December 2015
Non-validated questionnaire [Baseline questionnaire]	1	14 December 2015



Health Research Authority

Non-validated questionnaire [ATM 3 month participant questionnaires]	1	21 December 2015
Non-validated questionnaire [6 month participant questionnaire and blinding form]	1	21 December 2015
Notice of Substantial Amendment (non-CTIMP)	1	11 January 2016
Other [Post injection care and information]	2	21 December 2015
Other [ATM recruitment poster]	1	21 December 2015
Other [3 month thank you letter]	2.0	21 December 2015
Other [6 month questionnaire cover letter]	2.0	21 December 2015
Other [6 month thank you letter]	2.0	21 December 2015
Other [2 week follow up CRF]	1	21 December 2015
Other [PPR Preparation guide]	0.02	
Participant consent form	3.0	21 December 2015
Participant information sheet (PIS) [Summary]	3.0	21 December 2015
Participant information sheet (PIS) [Full]	4	10 February 2016
Research protocol or project proposal	2.0	21 December 2015

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

15/WM/0359:	Please quote this number on all correspondence
--------------------	---

Yours sincerely

PP

Dr Hilary Paniagua
Chair

E-mail: nrescommittee.westmidlands-blackcountry@nhs.net

Enclosures: List of names and professions of members who took part in the

Re-issued 02.03.16 following a correction to the approved documents list.



Health Research Authority

review

Copy to:

Mrs Ceri Jones, University Hospitals Coventry and Warwickshire

Dr Rebecca Kearney, University of Warwick

Mrs Jane Prewett



Health Research Authority

West Midlands - Black Country Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 05 February 2016

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Joseph Arumainayagam	Consultant and Honorary Senior Clinical Lecturer in HIV and GUM	Yes	
Dr Hilary Paniagua (Chair)	Senior Lecturer	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Lindsey Wallace	REC Assistant