

08 April 2016

Dr Rebecca Kearney
Clinical Lecturer
University of Warwick
Warwick Clinical Trials Unit, Warwick Medical School,
University of Warwick
Coventry
CV4 8UW

Dear Dr Kearney

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:	2
Amendment date:	29 March 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

There were no ethical issues raised.

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		29 March 2016
Notice of Substantial Amendment (non-CTIMP)	2	29 March 2016
Other [Letter to Trial Steering Committee members]		03 March 2016
Other [TSC Minutes]		11 February 2016
Other [6 Month questionnaire cover letter]	3	21 March 2016
Other [PIS Postal Cover letter]	1	11 January 2016
Other [Baseline questionnaire]	2	01 March 2016

Other [6 month participant questionnaire and blinding form]	3	21 March 2016
Other [3 month questionnaires]	2	01 March 2016
Other [2 week follow up CRF]	2	01 March 2016
Participant consent form	4	23 March 2016
Participant information sheet (PIS)	6	23 March 2016
Participant information sheet (PIS) [Summary]	4	01 March 2016
Research protocol or project proposal	3	03 March 2016

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
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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 review

*Copy to: Mrs Ceri Jones, University Hospitals Coventry and Warwickshire
Mrs Jane Prewett
Joanne O'Beirne-Elliman*

Health Research Authority

West Midlands - Black Country Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 01 April 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