

West Midlands - Black Country Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

13 December 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:	4
Amendment date:	21 November 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:

Document	Version	Date
Covering letter on headed paper		15 November 2016
Notice of Substantial Amendment (non-CTIMP)	4	21 November 2016
Other [E-mail correspondence]		25 November 2016
Other [Script for Text Messages]	1	09 June 2016
Other [ATM 2 week Follow up CRF – bilateral]	3	30 September 2016
Other [ATM 2 week Follow up CRF - single]	3	30 September 2016
Research protocol or project proposal	4	30 September 2016

Membership of the Committee

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

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.


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 Research Ethics 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
Chai**

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*

Attendance at Sub-Committee of the REC meeting on 09 December 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