



Health Research Authority

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.

25 May 2017

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:	Substantial Amendment 7 21-APR-2017
Amendment date:	21 April 2017
IRAS project ID:	187315

The above amendment was reviewed on 25 May 2017 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.

The Sub-Committee were in agreement that the Substantial Amendment did not raise any material ethical issues.

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 [ATM 6 Month Questionnaire Cover Letter - Reminder]	1.0	21 February 2017
Covering letter on headed paper [Amendment 7 Cover Letter_Final]		21 April 2017
Non-validated questionnaire [ATM 2 week Follow up CRF]	4.0	07 April 2017
Non-validated questionnaire [ATM 6 month Participant Questionnaires Bilateral]	4.0	07 April 2017
Non-validated questionnaire [ATM 6 month Participant Questionnaires Single]	4.0	07 April 2017
Non-validated questionnaire [ATM 3 month Participant Questionnaires Single]	3.0	07 April 2017
Non-validated questionnaire [ATM 3 month Participant Questionnaires Bilateral]	3.0	07 April 2017
Non-validated questionnaire [ATM 2 week Follow up CRF Bilateral]	4.0	07 April 2017
Notice of Substantial Amendment (non-CTIMP)	Substantial Amendment 7 21-APR-2017	21 April 2017
Other [Copy of Achilles Tendinopathy management hra-schedule-events-PIC]		21 April 2017
Other [Achilles Tendinopathy management statement-activities - PIC sites]		21 April 2017
Research protocol or project proposal [Clean]	6.0	21 April 2017
Research protocol or project proposal [Track Changes]	6.0	21 April 2017

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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P.P. Tanner

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

Copy to: Mrs Ceri Jones, University Hospitals Coventry and Warwickshire
Mrs Jane Prewett

West Midlands - Black Country Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 25 May 2017

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>
Ms Teagan Allen	REC Assistant