



Health Research Authority

West Midlands - Black Country Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

17 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

Thank you for submitting the above amendment, which was received on 17 May 2017. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee of the REC at its next meeting.

Documents received

The documents to be reviewed are as follows:

<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

Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

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 for the research.

We are pleased to welcome researchers and R & D staff at our Research Ethics Service 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



Teagan Allen
REC Assistant

Email: nrescommittee.westmidlands-blackcountry@nhs.net

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