

Welcome to the Integrated Research Application System**IRAS Project Filter**

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)

Achilles Tendinopathy Management

1. Is your project research?

☒ Yes ☐ No

2. Select one category from the list below:

- ☐ Clinical trial of an investigational medicinal product
- ☐ Clinical investigation or other study of a medical device
- ☐ Combined trial of an investigational medicinal product and an investigational medical device
- ☒ Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- ☐ Basic science study involving procedures with human participants
- ☐ Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- ☐ Study involving qualitative methods only
- ☐ Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
- ☐ Study limited to working with data (specific project only)
- ☐ Research tissue bank
- ☐ Research database

If your work does not fit any of these categories, select the option below:

☐ Other study

2a. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

☐ Yes ☒ No

2b. Please answer the following question(s):

- a) Does the study involve the use of any ionising radiation? ☐ Yes ☒ No
- b) Will you be taking new human tissue samples (or other human biological samples)? ☒ Yes ☐ No
- c) Will you be using existing human tissue samples (or other human biological samples)? ☐ Yes ☒ No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

- ☒ England
☐ Scotland
☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- ☒ England
☐ Scotland
☐ Wales
☐ Northern Ireland
☐ This study does not involve the NHS

4. Which applications do you require?

- ☐ IRAS Form
☒ NHS/HSC Research and Development offices
☐ Social Care Research Ethics Committee
☒ Research Ethics Committee
☐ Confidentiality Advisory Group (CAG)
☐ Her Majesty's Prison and Probation Service (HMPPS)

5. Will any research sites in this study be NHS organisations?

- ☒ Yes ☐ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or Medtech and In Vitro Diagnostic Cooperative in all study sites?

Please see information button for further details.

- ☐ Yes ☒ No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

- ☒ Yes ☐ No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

6. Do you plan to include any participants who are children?

☐ Yes ☒ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

☐ Yes ☒ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

☐ Yes ☒ No

9. Is the study or any part of it being undertaken as an educational project?

☐ Yes ☒ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

☐ Yes ☒ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

☐ Yes ☒ No

NOTICE OF SUBSTANTIAL AMENDMENT

*Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).
The form should be completed by the Chief Investigator using language comprehensible to a lay person.*

Details of Chief Investigator:

Title Forename/Initials Surname
Dr Rebecca Kearney

Work Address Warwick Clinical Trials Unit, Warwick Medical School,
University of Warwick
Coventry

PostCode CV4 8UW

Email R.S.Kearney@warwick.ac.uk

Telephone 02476153156

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For guidance on this section of the form refer to the guidance**Full title of study:**

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

Lead sponsor:

University of Warwick

Name of REC:

West Midlands - The Black Country Research Ethics Committee

REC reference number:

15/WM/0359

International Standard Randomised Controlled Trial Number (ISRCTN):**ClinicalTrials.gov Identifier (NCT number):****Additional reference number(s):**

Ref.Number	Description	Reference Number

Name of lead R&D office:

University Hospitals Coventry and Warwickshire

Date study commenced:**Protocol reference (if applicable), current version and date:**

v12.0

Amendment number and date:

Amendment 20 03.12.2019

Type of amendment

(a) Amendment to information previously given in IRAS

☒ Yes ☐ No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

(b) Amendment to the protocol

☒ Yes ☐ No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

☒ Yes ☐ No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified and not approved?

☐ Yes ☒ No

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.

If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.

If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

No cost extension to ensure recruitment target is achieved. New study timelines:

- May 2020 - End of recruitment
- October 2020 - End of follow-up
- February 2021 - End of study

Change to study protocol to update:

- Page 27 section 7.5 Trial timelines and milestones: Table removed and replaced with the below statement:
"Patient recruitment is planned to conclude on 31st May 2020, however, if the target of 240 patients in total is achieved before this date then recruitment will finish as appropriate.

Following the completion of patient recruitment, a period of 6 months is required to complete the patient follow up tasks along with a further 2 months to allow for result analysis and report compilation. It is therefore estimated that the trial will end February 2021, however, this is subject to change due to being dependent on recruitment rates."

Change to study documents to update with extension information and include a clarification around next of kin contact information:

- PIs

Section 6, page 3 – Rewording paragraph to be clearer around the use of text messages.

Section 6, page 4 and Section 13, page 5 – additional lines added in relation to next of kin contact information.

Section 14, page 5 – New recruitment and study timeline dates stated.

- Consent form

Bullet 1 – Updated document version number and date.

Bullet 9 – Clarification regarding text message consent and their use within the study.

- Transparency Statement

Rewording and layout updated to improve flow. Page one - following text added: "The legal basis for processing this

information under the GDPR is undertaking a task (research) in the public interest." and "The University of Warwick will process your next of kin's personal data; their name, address and phone number for the purpose(s) of making contact with them in relation to your participation in this clinical trial if we are unable to contact you. The legal basis for processing this personal data is legitimate interest. Your next of kin's personal data will not be shared or disclosed to any third parties external to the University of Warwick.

Please inform your next of kin of the above information if they are not already aware."

- Participant Letters

To ensure that participants are aware of where to find our data transparency statement we propose to add the below line to all letters send to participants directing them to the website:

"Please note that trial information, including our Data Transparency Statement and any subsequent updates, can be found on the trial website at: <https://warwick.ac.uk/fac/sci/med/research/ctu/musculoskeletalandpain/atm>"

This would follow the formatting shown in document "ATM 3 Month Questionnaire Cover Letter v 2.1 03-DEC-2019".

For each of the below letters 0.1 will be added to the version number, the document date will be updated and the signature has been updated to reflect a change in personnel/ role:

- ATM 3 Month Questionnaire Cover Letter v 2.1 03-DEC-2019
- ATM 6 Month Questionnaire Cover Letter v 4.1 03-DEC-2019
- ATM 6 Month Questionnaire Cover Letter - reminder v2.1 03-DEC-2019
- ATM 3 Month Thank You v3.1 03-DEC-2019
- ATM 6 Month Thank You v3.1 03-DEC-2019
- ATM 6-month+ Voucher v2.1 03-DEC-2019
- ATM Placebo Unblinding letter v3.1 03-DEC-2019
- ATM_ PRP Unblinding letter v3.1 03-DEC-2019

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

List of enclosed documents

<i>Document</i>	<i>Version</i>	<i>Date</i>
ATM Protocol V13.0 25-NOV-2019 - Clean	13	26/11/2019
ATM Protocol V13.0 25-NOV-2019 - TRACKED	13	26/11/2019
ATM Consent Form V5.0 26-NOV-2019 - Clean	5	26/11/2019
ATM Consent Form V5.0 26-NOV-2019 - TRACKED	5	26/11/2019
ATM Transparency Statement V2.0 03-Dec-2019 - Clean	2	03/12/2019
ATM Transparency Statement V2.0 03-Dec-2019 - TRACKED	2	03/12/2019
ATM Patient information sheet - Full - V7.0 03-Dec-2019 - Clean	7	03/12/2019
ATM Patient information sheet - Full - V7.0 03-Dec-2019 - TRACKED	7	03/12/2019
ATM 3 Month Questionnaire Cover Letter v 2.1 03-DEC-2019	2.1	03/12/2019

Declaration by Chief Investigator

1. *I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.*
2. *I consider that it would be reasonable for the proposed amendment to be implemented.*

This section was signed electronically by Dr Rebecca Kearney on 09/12/2019 01:05.

Job Title/Post:	Associate Professor
Organisation:	Warwick University
Email:	r.s.kearney@warwick.ac.uk

Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

This section was signed electronically by Mrs Jane Prewett on 11/12/2019 13:21.

Job Title/Post:	Head of Research Governance
Organisation:	Warwick University
Email:	jane.prewett@warwick.ac.uk