

# Diclofenac for Achilles tendon pain

<b>Submission date</b> 30/10/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/11/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/10/2019	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Chronic Achilles tendinopathy (CAT), a painful condition, is prevalent in the general population, and yet no program has been developed which can successfully treat this disorder in all cases. Recent evidence has shown that pain may be a limiting factor in a person's ability to rehabilitate their Achilles tendon. In order to help researchers develop a more effective rehabilitation program for tendinopathies, the aim of this study is to investigate the effects of topical diclofenac on individuals with CAT.

### Who can participate?

People aged 19 or over with Achilles tendinopathy

### What does the study involve?

Participants will be randomized to receive 10% topical diclofenac (an anti-inflammatory gel), or placebo (gel only, no drug). They will be asked to come into the study centre to have some baseline measurements of pain taken. The same measurements will be retaken after 4 weeks of treatment. This marks the end of the treatment period. There will be a final follow-up, by phone or email, at 12 weeks.

### What are the possible benefits and risks of participating?

There are no known benefits of participating, because the clinical efficacy of this treatment has not yet been established. A previous study showed that 10% diclofenac can have a short-term analgesic effect for Achilles tendinopathy, but its longer term effect (i.e. over a 4 week period) is not known.

Some participants can experience an allergic reaction to the gel - symptoms include a rash and /or itchiness. In theory, some subjects could experience a gastrointestinal bleed due to diclofenac entering the circulation. Symptoms would include stomach pain and bloody stool.

### Where is the study run from?

Fortius Sport and Health (Canada)

### When is the study starting and how long is it expected to run for?

April 2018 to January 2021 (updated 07/10/2019, previously: January 2020)

Who is funding the study?  
Foundation for Physical Medicine and Rehabilitation (USA)

Who is the main contact?  
Alex Scott  
ascott@mail.ubc.ca

## Contact information

**Type(s)**  
Public

**Contact name**  
Dr Alex Scott

**Contact details**  
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Vancouver  
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## Additional identifiers

**Protocol serial number**  
2017 Scott F. Nadler PASSOR Musculoskeletal Research Grant project

## Study information

**Scientific Title**  
Topical diclofenac vs placebo for Achilles tendinopathy - a randomized controlled trial

**Acronym**  
D4AT

**Study objectives**  
Individuals treated with topical diclofenac will have a greater improvement in VISA-A score at 4 weeks than those treated with placebo gel.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
University of British Columbia Clinical Research Ethics Board, 06/04/2018, H18-00181

**Study design**  
Interventional randomised controlled trial

**Primary study design**  
Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Achilles tendinopathy

**Interventions**

Participants will be randomised in a 1:1 ratio to receive 10% diclofenac treatment or an identical-appearing placebo gel. 1 g of the allocated gel will be massaged into a painful area of the tendon as needed over 4 weeks, up to 3 times daily.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Diclofenac

**Primary outcome(s)**

Severity of Achilles tendinopathy, assessed using the VISA-A score at the baseline and after 4 and 12 weeks

**Key secondary outcome(s)**

The following are assessed at the baseline and after 4 and 12 weeks:

1. Pain, assessed using Numeric Pain Rating Scale
  - 1.1. Average pain during all tendon loading activities over last week
  - 1.2. Average pain during rehabilitative exercise over last week
  - 1.3. Average pain at rest during last week
  - 1.4. Current resting pain
2. Patient-reported change in symptoms, assessed using a 7 point scale from substantially better to substantially worse
3. Pressure pain threshold (N), assessed using an algometer
4. transverse tendon stiffness (N/m) measured over the site of maximum tendon stiffness using the MyotonPro

**Completion date**

30/01/2021

**Eligibility****Key inclusion criteria**

1. Aged 19 years and older
2. Fluent in English
3. Previously diagnosed with Achilles tendinopathy by a health care professional (imaging at the discretion of the treating physician) and demonstrating the following criteria:
  - 3.1. Localized tendon pain and thickening, worsened with palpation and tendon loading activities
  - 3.2. No clinical suspicion of other diagnoses
4. Symptoms for 3 months or more

5. Able to give informed consent
6. VISA-A score less than 80
7. Engaged in an active rehabilitation program prescribed by an exercise specialist

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. BMI > 30.0.
2. Previous Achilles tendon rupture (complete or partial)
3. Diagnosed with chronic pain syndrome, diabetes, hyperprproteinemia, metabolic syndrome, or systemic inflammatory diseases
4. History of gastric ulcers, kidney disease or unstable hypertension
5. Symptomatic osteoarthritis of the spine or lower extremities
6. Received corticosteroid injections in the Achilles region
7. Regularly take non-steroidal anti-inflammatory medication
8. Prescribed anticoagulants or fluoroquinolones within the past 5 months
9. Allergies to diclofenac or the placebo cream
10. Unable to give informed consent

**Date of first enrolment**

06/04/2018

**Date of final enrolment**

30/09/2020

**Locations****Countries of recruitment**

Canada

**Study participating centre****Fortius Sport and Health**

3713 Kensington Ave,

Burnaby

Canada

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# Sponsor information

## Organisation

University of British Columbia

## ROR

<https://ror.org/03rmrcq20>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Foundation for Physical Medicine and Rehabilitation

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Alex Scott ([ascott@mail.ubc.ca](mailto:ascott@mail.ubc.ca)). The anonymized, primary and secondary outcome data will be emailed on request to academics or clinician-scientists for the purposes of systematic review or metaanalysis. Our consent form allows the anonymized data to be used for scientific purposes, which is generally understood to including sharing of the data with other scientists. There is a specific proviso in the consent form that a participant may request their data to be withdrawn from the study, but that this may not be possible if it has already been merged with other databases. The consent form contains the following statement:

"Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator and UBC Clinical Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a subject in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected. You also have the legal right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor."

**IPD sharing plan summary**

Available on request