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Diclofenac for Achilles tendon pain

Submission date
30/10/2018

Recruitment status
No longer recruiting

Registration date
12/11/2018

Overall study status
Completed

Last Edited
07/10/2019

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2017 Scott F. Nadler PASSOR Musculoskeletal Research Grant project

Study information

Scientific Title
Topoical 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

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

Secondary outcome measures
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

Overall study start date
01/04/2018

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

Age group
Adult

Sex
Both

Target number of participants
100

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
V5B 0A7

Sponsor information

Organisation
University of British Columbia

Sponsor details
2177 Wesbrook Mall
Vancouver
Canada
V6T2A1

Sponsor type
University/education

Website
www.ubc.ca

ROR
https://ror.org/03rmrcq20

Funder(s)

Funder type
Research organisation

Funder Name
Foundation for Physical Medicine and Rehabilitation

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2021

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). 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