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Diclofenac for Achilles tendinopathy

Submission date
29/06/2015

Recruitment status
No longer recruiting

Registration date
03/07/2015

Overall study status
Completed

Last Edited
08/05/2017

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic Achilles tendinopathy is a clinical condition characterized by a breakdown of the Achilles tendon. Chronic means persisting for a long time or to constantly reoccur. Achilles tendinopathy is a common injury usually caused by tendon overuse due to repetitive movements. Symptoms of chronic tendinopathy are stiffness, swelling, and pain. Exercise is painful for patients to perform and limits patients from executing movements properly. This hinders their ability to recover quickly and successfully. The exact causes of the pain are unclear and there is currently no gold standard treatment for rehabilitating this chronic condition. The purpose of this research is to see if a non-steroidal anti-inflammatory drug, diclofenac, will be able to relieve pain in chronic tendinopathy. The effects of diclofenac on patients will be evaluated at rest and during simple calf exercises. It is expected that diclofenac will reduce pain among patients with Achilles tendinopathy. With proper pain relief, future studies can look at using the application of diclofenac in combination with gradual exercise to develop a better rehabilitation program. We also want to get a better understanding of how chronic pain affects patients. The study will compare the pain threshold between healthy and tendinopathic tendons. This study takes an innovative approach on how to manage Achilles tendon pain in a rehabilitation setting. It is anticipated that the results will create a new understanding of how tendinopathies can be treated and how pain is regulated in tendons.

Who can participate?
Adults (aged at least 19) who have had Achilles pain for at least 3 months.

What does the study involve?
Participants agreeing to take part in the study are asked to do the following: complete 2 questionnaires, supply demographic information (for example gender, age, education etc), give weight and height measurements, answer medical questions and undergo ultrasound imaging, a single-leg hopping test and a pain pressure threshold test. The duration of the study is 5 weeks. After being checked for eligibility and giving consent, all participants undergo initial pain measurements, ultrasound scans, pain pressure threshold test and hoping test . The hopping test consist of 25 rhythmic hops, at a self-selected/comfortable pace (approx. 2 jumps/second), on one leg, first on the unaffected side, and then on the affected side (15 second rest between each leg). At the end of the hopping, the degree of pain experienced by the participant is recorded. The participants are then issued with either a randomized placebo or 10% diclofenac gel. They are instructed to apply the gel every 8 hours/3 times a day for 3 days before the next

scheduled appointment. The second appointment is scheduled within 3 days to 1 week following the initial appointment. At the start of the visit, each participant is asked which treatment they thought they received, any remaining gel is collected, and they are asked whether their condition has worsened, improved, or stayed the same. Each participant then repeats the hopping test, and pain-pressure threshold test. The participants are then given their second tube of gel (placebo or diclofenac) to apply at home. Each participant is then asked to come back on one more occasion within 10 days to 2 weeks following the previous appointment, where they are required to repeat the same assessments once more.

What are the possible benefits and risks of participating?
It is hoped that diclofenac will improve activity-related pain and function in participation with Achilles tendinopathy. Diclofenac has successfully been used as treatment for elbow tendinopathy but has not been previously used on Achilles tendinopathy. Participants may or may not clinically benefit from participation in the study. They may also experience a rash, dry skin, an allergic reaction, gastro-intestinal discomfort, indigestion, nausea, vomiting, diarrhea, or constipation. The side-effects associated with topical diclofenac are rare. To minimize harms, participants will be unblinded and may withdraw from the study if adverse effects occur or are suspected to be occurring.

Where is the study run from?
Centre for Hip Health and Mobility (CHHM), Vancouver, BC (Canada)

When is the study starting and how long is it expected to run for?
September 2014 to March 2016

Who is the main contact?
Ms Erin Bussin
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Contact information

Type(s)
Scientific

Contact name
Ms Erin Bussin

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomized controlled trial to evaluate the effects of topical diclofenac on the pain associated with chronic achilles tendinopathy: a pilot study

Study objectives
Individuals treated with topical diclofenac will have a clinically significant reduction in pain during tendon loading than when treated with placebo gel.

Ethics approval required
Old ethics approval format

Ethics approval(s)
UBC Clinical Research Ethics Board, 28/07/2015, ref: H15-00999

Study design
Single-centre pilot crossover randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Achilles tendinopathy

Interventions
This study has a crossover design. All 32 participants will be receiving the treatment and the placebo. This study is double-blinded. Whether or not participants receive the drug treatment for visit 2 or visit 3 will be determined by chance (e.g. coin flip). The dosage in this study is 80 mg of diclofenac (1 gm of 10% diclofenac) three times a day (every 8 hours) for 3 days. There is no follow-up.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Measured at baseline, 1 week, day 10, and day 23

Assessment of tendon pain while performing 25 single-leg hops on the painful side, rated verbally using the numeric pain rating scale. The hopping test consists of 25 rhythmic hops, at a self-selected/comfortable pace (approx. 2 jumps/second), on one leg, first on the unaffected side, and then on the affected side (15 second rest between each leg).). At the end of the hopping, the subject's pain level will be recorded using a pain numeric rating scale (0-10).

Secondary outcome measures
Measured at baseline, 1 week, day 10, and day 23

1. Assessment of pressure pain threshold (PPT) using an Algometer, on the Achilles tendon, and at an unrelated location (the trapezius muscle) to examine for potential effects of the treatment on central pain processing.). The investigator will use the AlgoMed Algometer to assess the subject's pain pressure threshold (PPT) on the trapezius muscle (bilaterally) and on both Achilles tendons. Testing will be conducted at a controlled rate (30 KPa/s) with the subject lying prone on a treatment plinth. Pressure is gradually applied until the subject first experiences onset of pain, at which point they push a button. In rare cases where the person with CAT has baseline (resting) pain, then they will be instructed to press the button at the first increase in pain.
2. Assessment of lower limb kinematics during single-leg multiple hops using the LEONARDO Mechanography Ground Reaction Force Platform (GRFP) to determine the maximum force generated (normalized to body mass of participant) and leg stiffness.

Overall study start date
01/09/2014

Completion date
01/03/2016

Eligibility

Key inclusion criteria
1. Male and female subjects aged 19 years and older
2. Fluent in English
3. Subjects previously diagnosed with Achilles tendinopathy by a health care professional and demonstrating the following criteria – localized tendon pain and thickening, worsened with palpation and tendon loading activities, and no clinical suspicion of other diagnoses
4. Symptoms for 3 months or more
5. Subjects who are able to give informed consent
6. VISA-A score less than 80
7. Pain score (numeric pain rating scale) greater than 2/10 when performing a hopping test (25 single leg hops on the painful side)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
32

Key exclusion criteria
1. Male and female subjects aged 18 years and younger
2. Subjects with a BMI greater than 30.0
3. Subjects with previous Achilles tendon rupture
4. Subjects diagnosed with pain syndrome, diabetes, hyperproteinemia, metabolic syndrome, or systemic inflammatory diseases
5. Subjects with symptomatic osteoarthritis of the spine or lower extremities
6. Subjects who have received corticosteroid injections
7. Subjects who take non-steroidal anti-inflammatory medication regularly
8. Subjects who have been prescribed statins, anticoagulant, or fluroquinolones within the past 3 months
9. Subjects with allergies to diclofenac or placebo cream
10. Subjects who are unable to give informed consent

Date of first enrolment
27/07/2015

Date of final enrolment
01/02/2016

Locations

Countries of recruitment
Canada

Study participating centre
Centre of Hip Health and Mobility
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Sponsor information

Organisation
University of British Columbia

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Sponsor type
University/education

ROR
https://ror.org/03rmrcq20

Funder(s)

Funder type
University/education

Funder Name
University of British Columbia

Alternative Name(s)
University of British Columbia in Canada, UniversityofBC, The University of British Columbia, UBC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/05/2017		Yes	No