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Intramuscular stimulation and eccentric exercise versus eccentric exercise plus sham needling for the treatment of chronic midportion Achilles tendinopathy

Submission date
26/07/2012

Recruitment status
No longer recruiting

Registration date
30/08/2012

Overall study status
Completed

Last Edited
07/05/2021

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this study is to find out whether Achilles tendon pain (tendinopathy) can be treated more effectively if a form of treatment called IMS (intramuscular stimulation) is added to the current standard treatment programme.

Who can participate?
Men and women between the ages of 19 and 60 who have pain in the area of the Achilles tendon.

What does the study involve?
Participants will attend a screening assessment with a registered physiotherapist to find out if they are suitable for this study. If they are found to be suitable, they will then have an Ultrasound Tissue Characterisation Scan (UTC) image taken of the affected tendon. This scan will provide information on the structure of the tendon and will take about five minutes. Participants will also be asked to have another UTC scan after 6 weeks of treatment, at the end of the study (after 12 weeks of treatment), and at 12 months. Participants will be randomly placed into one of two groups. All participants will be asked to complete a set of exercises twice a day. Each set of exercises will take about five minutes to complete. Group 1 will receive the current standard of treatment for Achilles pain and receive IMS. Group 2 will receive the current standard of treatment and treatment that is like IMS but is not IMS (placebo). Participants will fill out a questionnaire which will take about 5 minutes to complete. This questionnaire will tell us how severe the tendon problem is. Participants will be asked to fill this questionnaire out five times: at the beginning of the study, before starting treatment, after 6 weeks of participation in the study, at the end of treatment (after 12 weeks of participation in the study), and one year after the beginning of the study, for long-term follow-up. Participants will have the amount of movement in the ankle measured by a physiotherapist three times - at the beginning of the study, after 6 weeks of participation in the study, and at the end of treatment and at 12 months. This will take about 5 minutes each time. All participants will attend nine physiotherapy visits over 12 weeks. Each visit will take about 45 minutes and they will be spread out so that the first

six visits are about one week apart and the last three visits are about two weeks apart. The physiotherapist will teach the tendon exercises and check that these exercises are being performed correctly.

What are the possible benefits and risks of participating?
No matter which group participants are allocated to, they will be provided with the current standard of care for Achilles pain which has a 60-80% success rate. If allocated to the IMS-like group, participants would be expected to have similar results. If allocated to the IMS group, participants may or may not derive extra benefit from IMS treatment. If it is found that IMS does add extra benefit, this information will be used to help others who have Achilles pain. The exercise to stimulate healing in the tendon is likely to be uncomfortable. In fact, it has been proven that for the exercises to work best there needs to be some discomfort in the tendon. The physiotherapist will instruct participants to keep the discomfort to a level of no more than 5/10 on a scale of 0 to 10 where 0 is no pain at all and 10 is the worst possible imaginable pain.
The potential risks of IMS or IMS-like (placebo) treatment are:
1. Aching/increased pain: There may be an increase in pain for one or two days, followed by an improvement in the overall pain state. This happens very commonly (50% or greater).
2. Bruising: A needle may be placed inadvertently in a blood vessel. If blood vessel is punctured with the needle, a hematoma (or bruise) will develop. This happens less commonly (5-20%).
3. Parasthesia: If a nerve is punctured, it may cause paresthesia (a prickling sensation) which may continue for days. This happens less commonly (5-20%).
4. Dizziness or faintness: Treatment may induce faintness or dizziness of a brief duration and which does not typically last beyond the time of your treatment session. This happens rarely (less than 2%).
5. Infection: This occurs any time a needle is used. For this study, sterile disposable needles will be used. This happens rarely (less than 2%).
6. Pneumothorax: When a needle is placed close to the chest wall, there is a rare possibility of pneumothorax (air in the chest cavity). This happens rarely (less than 2%).
Fortunately all these complications are not fatal and are readily reversible.

Where is the study run from?
The study is run by the University of British Columbia and UTC scans are performed at:
1. Kinetic Rehabilitation Centre, North Vancouver, British Columbia, Canada
2. Canopy Integrated Health, North Vancouver, British Columbia, Canada
3. The Centre for Hip Health and Mobility, Vancouver General Hospital, Vancouver, British Columbia, Canada

When is the study starting and how long is it expected to run for?
January 2013 to December 2018

Who is funding the study?
University of British Columbia - Chan Gunn IMS/Neuropathic Pain Research Fund (Canada)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
H12-02008

Study information

Scientific Title
Intramuscular stimulation and eccentric exercise vs eccentric exercise plus sham needling for the treatment of chronic midportion Achilles tendinopathy: a randomized controlled clinical trial

Study objectives
Current hypothesis as of 08/08/2014:
1. Intramuscular stimulation (IMS) will lead to improved clinical outcomes in patients with Achilles tendinopathy, compared to standard treatment with placebo treatment.
2. The sham needling group will improve on average by 20 VISA-A points after 12 weeks, and that the IMS group will improve by a further 15 points (considered to be a clinically significant difference).

Previous hypothesis:
1. Intramuscular stimulation (IMS) will lead to improved clinical outcomes in patients with Achilles tendinopathy, compared to standard treatment with or without placebo treatment.
2. No-needling and sham needling groups will improve on average by 20 VISA-A points after 12 weeks, and that the IMS group will improve by a further 15 points (considered to be a clinically significant difference).

Ethics approval required
Old ethics approval format

Ethics approval(s)
UBC Clinical Research Ethics Board, 17/08/2012, ref: H12-02008

Study design
Prospective single-blind randomized controlled trial with two arms

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Current interventions as of 30/10/2012:
IMS treatment group
Intramuscular Stimulation (IMS) involves the insertion of fine sterile needles into tender and painful points in tight muscle bands. Treatment will be guided by the findings of the assessment, which will have paid particular attention to signs in groupings of muscles supplied by both the dorsal and ventral rami of the same segmental spinal level. Muscles in the periphery that have demonstrated tight bands or reduced muscle lengths will be treated with IMS by one of the investigators (LS). Muscles at levels of the spine that have demonstrated tight muscle bands, signs of trophedema or tender, prominent spinous processes will also be treated. The IMS group will receive treatment once a week for the first 6 weeks of the trial and once every 2 weeks for the remainder, resulting in nine treatments overall. Total treatment duration is approximately 4. 5 hours.

Sham needling
The appropriate control for acupuncture or needling studies is always controversial, as the act of needling nonspecifically, even superficially, can induce a variety of physiological responses as well as a variable level of placebo response. Nonetheless, recently the importance of including both sham needling and no-treatment controls has been emphasized, and considered superior to non-penetrating placebo needles. In the sham needling group, eight acupuncture needles will be inserted into the dermis of the buttock, posterior thigh and calf and will be left in situ for ten minutes. The timing and duration of sham needling treatments is the same as the IMS treatment group arm. Total treatment duration is approximately 4. 5 hours.

Training program
Both groups will undertake an exercise programme designed to initially maintain and then, as tolerated, increase the ability of the muscle-tendon unit and kinetic chain to absorb load. There will be four stages in this programme. Eccentric exercises consisting of gastrocnemius-soleus-Achilles tendon complex loading (ELE) will be incorporated at each stage. Eccentric loading has been demonstrated to be the most consistently effective conservative intervention in the treatment of mid-portion Achilles tendinosis. The program will be modeled on those developed by Alfredson and colleagues and Silbernagel and colleagues. Eccentric exercises will be prescribed in a progressive manner for the 12-week duration of the trial. Exercise progression will be as follows: two-legged very slow (Stage 1a) to slow (Stage 1b) eccentric exercise to plantargrade (on flat ground) adding load with weighted backpack or resistance equipment as available (Stage 1a progressing to Stage 1b). The next level of exercises (Stage 2) will progress to single-legged slow eccentric exercise into dorsiflexion, adding load with weighted backpack or resistance equipment as available. Further progression of loading will then be achieved by introducing speed to previously prescribed exercises using only body weight as resistance (Stage 3). Those participants who reach Stage 4 will be prescribed sports-specific exercises aimed at increasing the capacity of the muscle-tendon unit to absorb elastic loading to functional levels. Stage 1 exercises will be prescribed two to three times a day. Stage 1b exercises will be

prescribed once a day, every other day. Stage 2 exercises will be prescribed every other day. Stage 3 exercises will be prescribed once a day every third day. All subjects on progression from Stage 1 to Stage 2 of the rehabilitation programme will have a scheduled rest day. On commencement of Level 2 exercises, Stage 1 and 2 level exercises will be alternated for 6 days of the week and the seventh day will be allocated as a rest day. Once Stage 3 exercises are added, Stage 1, 2 and 3 exercises will be alternated for 6 days of the week and the seventh day will be allocated as a rest day. All subjects will be entered into the rehabilitation programme at Stage 1. Subjects will be progressed based on a 24-hour response to exercise; specifically there must not be pain or stiffness the morning after undertaking the exercise. Pain during exercises will be allowed as long as it is not more than 5/10 pain on a 0 to 10 scale, where 0 is no pain at all and 10 is the worst possible imaginable pain. Through all four stages, those subjects in the IMS group and the sham needling group will be advised to rest from their ELE and exercise generally (including stretches) after their treatment for the remainder of the day and the entire next day. From Stage 2 on, this rest day will be scheduled to coincide with the day seven rest day that all groups will observe. They will be instructed to recommence their exercise program the morning after. This is standard advice given to patients receiving IMS treatment.

All subjects will be advised that they may participate in pain-provoking activity, such as running, as long as their pain does not reach greater than 5/10 (Visual Analogue Scale) during the activity and as long as pain has returned to baseline by the following morning. The provocation of this level of pain during rehabilitation has been shown to not hinder recovery.

The exercise technique and progression will be reviewed every two weeks until 12 weeks (6 reviews total). Total treatment duration is approximately 3 hours.

Previous interventions until 30/10/2012:
Training program
All three groups will undertake an eccentric exercise program consisting of gastrocnemius-soleus-Achilles tendon complex loading (ELE). Eccentric loading has been demonstrated to be the most consistently effective conservative intervention in the treatment of mid-portion Achilles tendinosis. The program will be modeled on those developed by Alfredson and colleagues and Silbernagel and colleagues. Eccentric exercises will be prescribed as three sets of 15 repetitions twice a day, both with a straight knee and a bent knee (to preferentially recruit the soleus muscle), for the 12-week duration of the trial. Exercise progression will be as follows: two-legged slow eccentric exercise to plantargrade (on flat ground) progressing to two-legged slow eccentric exercise into dorsiflexion (over a step), then to single-legged slow eccentric exercise into dorsiflexion. Further progression of loading will then be achieved by adding weights in a backpack or similar. The initial magnitude of loading prescribed will be determined by the subjects pain response to the load and ability to conduct the exercise correctly (e.g., no overpronation). Subjects who complain of pain with activities of daily living will begin with two-legged eccentric loading to plantargrade. They will progress to the next level of loading once this level no longer provokes pain. Subjects who only have pain with exercise will begin with exercises into dorsiflexion. These subjects will be placed in a loading level based on where pain is provoked, but does not cause more than 5/10 pain on a 0 to 10 scale, where 0 is no pain at all and 10 is the worst possible imaginable pain. Once this load no longer provokes a pain response, they will be progressed to the next level. Once pain can no longer be provoked before the onset of fatigue with sets of 15 repetitions, a 15-repetition maximum load will be prescribed. Those subjects in the IMS group and the sham needling group will be advised to rest from their ELE and exercise generally (including stretches) after their treatment for the remainder of the day and the entire next day. They will be instructed to recommence their exercise program the morning after. This is standard advice given to patients receiving IMS treatment.

All subjects will be advised that they may participate in pain-provoking activity, such as running, as long as their pain does not reach greater than 5/10 (Visual Analogue Scale) during the activity and as long as pain has returned to baseline by the following morning. The provocation of this level of pain during rehabilitation has been shown to not hinder recovery.

The exercise technique and progression will be reviewed every two weeks until 12 weeks (six reviews total). At the final review a maintenance program will be provided depending on the level of loading achieved: three sets of 15 repetitions, once a day, three or four times a week. Total treatment duration is approximately 3 hours.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Current primary outcome measures as of 11/04/2013:
The primary outcome measure for which the study is powered is the 12-week VISA-A score - a well-validated and reliable disease-specific outcome measure, which also includes an activity-related pain scale. Secondary outcome measures include treatment success/failure, and muscle length (dorsiflexion ROM). Patients will rate themselves from 0 (very much worse) to 6 (very much improved). Scores of very much improved or much improved will be categorized as successes. Dorsiflexion range of motion with knee bent and straight will also be measured, giving an indication of the effect of IMS and exercise vs exercise alone on muscle extensibility. These measures will be taken at 0 weeks, 12 weeks, 6 months, and 52 weeks. At 12 weeks a follow-up UTC scan will be conducted to determine, as a pilot study, whether there is any subjective indication of a potential effect of IMS on tissue remodeling that could be pursued with a mechanistic study in future.

Muscle length measures will be made according to the protocol described by Norkin and White and Kendall and colleagues by a paid, experienced physiotherapist unaware of the treatment allocation. The two-joint plantarflexors (gastrocnemius and plantaris) will be measured in supine with the knee extended. The one-joint plantarflexors will also be measured in supine but with the hip and knee flexed 90 degrees or more to make the two-joint plantar flexors slack across the knee joint. The ankle will be passively dorsiflexed and the angle achieved measured by inclinometry. The fulcrum will be centred over the lateral aspect of the lateral malleolus, the proximal arm will be aligned with the lateral midline of the fibula, using the head of the fibula for reference, and the distal arm will be positioned parallel to the lateral aspect of the fifth metatarsal. The ankle will be dorsiflexed to end-of-range (firm muscular end-feel) by pushing upward across the plantar surface of the metatarsal heads, without allowing the foot to rotate into inversion or eversion. Intratester reliability in measuring passive ankle dorsiflexion by goniometry has been shown to have an Intraclass Correlation Coefficient (ICC) of 0.91 for more experienced therapists.

Previous primary outcome measures as of 30/10/2012:
The primary outcome measure for which the study is powered is the 12-week VISA-A score - a well-validated and reliable disease-specific outcome measure, which also includes an activity-related pain scale. Secondary outcome measures include treatment success/failure, and muscle length (dorsiflexion ROM). Patients will rate themselves from 0 (very much worse) to 6 (very much improved). Scores of very much improved or much improved will be categorized as

successes. Dorsiflexion range of motion with knee bent and straight will also be measured, giving an indication of the effect of IMS and exercise vs exercise alone on muscle extensibility. These measures will be taken at 0, 6 and 12 weeks, as well as at 52 weeks. At 12 weeks a follow-up UTC scan will be conducted to determine, as a pilot study, whether there is any subjective indication of a potential effect of IMS on tissue remodeling that could be pursued with a mechanistic study in future.

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Previous primary outcome measures until 30/10/2012:
The primary outcome measure for which the study is powered is the 12-week VISA-A score - a well-validated and reliable disease-specific outcome measure, which also includes an activity-related pain scale. Secondary outcome measures include treatment success/failure, and muscle length (dorsiflexion ROM). Patients will rate themselves from 0 (very much worse) to 6 (very much improved). Scores of very much improved or much improved will be categorized as successes. Dorsiflexion range of motion with knee bent and straight will also be measured, giving an indication of the effect of IMS and exercise vs exercise alone on muscle extensibility. These measures will be taken at 0, 6 and 12 weeks, as well as at 52 weeks. At 12 weeks a follow-up ultrasound scan will be conducted to determine, as a pilot study, whether there is any subjective indication of a potential effect of IMS on tissue remodeling that could be pursued with a mechanistic study in future.

Muscle length measures will be made according to the protocol described by Norkin and White and Kendall and colleagues by a paid, experienced physiotherapist unaware of the treatment allocation. The two-joint plantarflexors (gastrocnemius and plantaris) will be measured in supine with the knee extended. The one-joint plantarflexors will also be measured in supine but with the hip and knee flexed 90 degrees or more to make the two-joint plantar flexors slack across the knee joint. The ankle will be passively dorsiflexed and the angle achieved measured by goniometry. The fulcrum will be centred over the lateral aspect of the lateral malleolus, the proximal arm will be aligned with the lateral midline of the fibula, using the head of the fibula for reference, and the distal arm will be positioned parallel to the lateral aspect of the fifth metatarsal. The ankle will be dorsiflexed to end-of-range (firm muscular end-feel) by pushing upward across the plantar surface of the metatarsal heads, without allowing the foot to rotate into inversion or eversion. Intratester reliability in measuring passive ankle dorsiflexion by goniometry has been shown to have an Intraclass Correlation Coefficient (ICC) of 0.91 for more experienced therapists.

Key secondary outcome(s))

1. Global improvement scale
2. Dorsiflexion range of motion

Completion date
01/07/2019

Eligibility

Key inclusion criteria
Current inclusion criteria as of 30/10/2012:
1. Aged 19 to 60 years of age with a 3-month minimum symptom duration
2. Evidence of midportion Achilles tendinopathy by history and on physical examination
3. Objective signs by Gunn IMS assessment of neuropathic change in the L5-S2 segmental levels including the presence of taut muscle bands amenable to IMS. Tight bands palpated in muscles paraspinally (dorsal rami) from T1 down and peripherally (ventral rami) from T12 down will also be treated in the IMS group participants

Previous inclusion criteria until 30/10/2012:
2. Evidence of midportion Achilles tendinopathy on physical examination and tendinosis on ultrasound

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
54

Key exclusion criteria
Current exclusion criteria as of 15/09/2014:
1. IMS contraindications:
1.1. Infection in the area
1.2. Pregnancy
1.3. Bleeding disorders
1.4. History of bacterial endocarditis
1.5. Post-surgical implant in last 4-6 months and major surgery in the last 3 months
2. Previous treatment with IMS or TCMA (for blinding purposes)
3. True leg length difference of greater than half and inch
4. Previous corticosteroid injections or recent fluoroquinolone use and systemic inflammatory disease.
5. Those demonstrating the presence of other syndromes that cause pain in and around the

Achilles, e.g.:
5.1. Partial tearing
5.2. Posterior ankle impingement/os trigonum syndrome
5.3. Dislocation of the peroneal or other plantar flexor tendons
5.4. Irritation or neuroma of the sural nerve or insertional Achilles pain

Exclusion criteria from 30/10/2012 to 15/09/2014:
1. IMS contraindications:
1.1. Infection in the area
1.2. Pregnancy
1.3. Bleeding disorders
1.4. History of bacterial endocarditis
1.5. Post-surgical implant in last 4-6 months and major surgery in the last 3 months
2. Previous treatment with IMS or TCMA (for blinding purposes)
3. True leg length difference of greater than half and inch
4. Previous corticosteroid injections or recent fluoroquinolone use and systemic inflammatory disease.
5. Those demonstrating the presence of other syndromes that cause pain in and around the Achilles, e.g.:
5.1. Partial tearing
5.2. Posterior ankle impingement/os trigonum syndrome
5.3. Tenosynovitis
5.4. Dislocation of the peroneal or other plantar flexor tendons
5.5. Irritation or neuroma of the sural nerve or insertional Achilles pain

Original exclusion criteria until 30/10/2012:
5. Those demonstrating the presence of other syndromes that cause pain in and around the Achilles, e.g.:
5.1. Partial tearing
5.2. Posterior ankle impingement/os trigonum syndrome
5.3. Tenosynovitis
5.4. Dislocation of the peroneal or other plantar flexor tendons
5.5. An accessory soleus muscle
5.6. Irritation or neuroma of the sural nerve or insertional Achilles pain

Date of first enrolment
15/04/2013

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Canada

Study participating centre
University of British Columbia
Vancouver

Canada
V5Z1M9

Sponsor information

Organisation
University of British Columbia (Canada)

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), The University of British Columbia, UBC The University of British Columbia, UBC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are available from Alex Scott (ascott@interchange.ubc.ca) on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/09/2020	07/05/2021	Yes	No