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The time course of pain relief provided by acupuncture in treatment of tennis elbow

Submission date
17/02/2015

Recruitment status
No longer recruiting

Registration date
25/02/2015

Overall study status
Completed

Last Edited
09/08/2017

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
Tennis elbow is a common disorder often caused by repetitive use or overloading of the arm. This condition can lead to difficulties in performing simple daily tasks, such as turning a door knob, holding a cup, or pulling up pants, due to pain. Rehabilitation exercise has shown to stimulate tendon healing and improve functional abilities of the arm in patients with tennis elbow. However, patients' fear of pain often hinder their motivation to participate in exercise programs. Thus, exercise is often combined with other treatments which can provide pain relief. For example, acupuncture, particularly electroacupuncture, may be a good option to combine with an exercise program. In electroacupuncture, a small amount of electrical current is applied to the region of the body through acupuncture needles. It is quite commonly used in clinical practice to reduce pain, esp. pain related to musculoskeletal disorders. The aim of this study is to compare the effects of standard acupuncture vs electroacupuncture in the treatment of tennis elbow for a 72-hour period after an intervention. In addition, the study investigates if the degree of pain relief produced by either intervention is significant enough to see changes in muscle strength and function. If the time course of pain relief provided by either intervention can be estimated, the best time to incorporate either intervention into a rehabilitation program can be determined in order to boost patients' active participation in exercise programs and to further enhance tendon repair.

Who can participate?
Patients aged between 19 and 65 who have had tennis elbow for longer than 6 weeks

What does the study involve?
Participants are randomly allocated to either the electroacupuncture or standard acupuncture group and receive treatment according to the group allocation. This study involves the penetration of skin with acupuncture needles at seven different acupoints. The depth of needling at each point will be about 1-3.5cm into the body. Only sterile, single-use, disposable stainless steel acupuncture needles are used. Both groups receive the same acupuncture treatment. The only difference between two groups is that, in the electroacupuncture group, participants also receive electro-stimulation over the lateral elbow and hand-forearm regions. This may involve a mild tingling sensation as electrical current is passed through the acupuncture needles. The treatment lasts 30 minutes in both groups.

What are the possible benefits and risks of participating?
Participants will find out if acupuncture treatment is helpful in pain relief for their elbow pain. There will be a $50 honorarium for participating in the study. Participants may experience: slight discomfort upon insertion of needles; numbness, mild electrical shock sensation that lasts a few seconds, distension, soreness, and occasional sharp pain; light-headed during or after treatment; mild bleeding, swelling, or bruising; allergic reaction to the metal needles, such as rashes or itching of skin-tingling sensation temporarily after electro-stimulation. However, there have been few side effects reported with acupuncture.

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

When is the study starting and how long is it expected to run for?
January 2015 to February 2016

Who is funding the study?
This study is not receiving funds from an external agency or sponsor. It is being conducted by Jaewon Jeon, who is a certified Traditional Chinese Medical practitioner and a Master of Science student in Rehabilitation Sciences, UBC.

Who is the main contact?
Jaewon Jeon
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
H15-00439

Study information

Scientific Title
The time course of the analgesic effect of acupuncture in treatment of lateral epicondylalgia (LE): a pilot study

Study objectives
1. Electroacupuncture will produce a greater analgesic effect compared to standard acupuncture.
2. The analgesic effect produced by acupuncture, particularly electroacupuncture, will be significant enough to see improvement in pain-free grip strength in patients with lateral epicondylalgia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethics Board (CREB) of the University of British Columbia, 30/03/2015, ref: H15-00439

Study design
Interventional single-center study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Lateral epicondylalgia or 'tennis elbow'

Interventions
Participants will be randomly assigned to receive one of two types of acupuncture treatment: electroacupuncture (EA) or standard acupuncture. A randomization list of 40 equally weighted allocations will be generated in REDCAP prior to the start of the study. The third person who is not involved in this study protocol will press a randomization button in REDCAP to produce the allocation code for each participant, after confirming the placement of needles by the clinician.

In both groups, participants will receive acupuncture on LI 4, SJ 5, LU 5, LI 10, LI 12, SP 6, and GB 34. Only sterile, single-use, disposable stainless steel needles will be used (Serin J-type, 40mm x 0.25mm) for both treatment groups. After inserting acupuncture needles into the skin to required depth (1.5- 3.5 cm), the clinician will manipulate acupuncture needles until patients feel deqi (arrival of qi). Deqi is a subjective feeling of a patient at the region where an acupuncture needle is inserted into the acupoint and it is characterized by aching, soreness, numbness, tingling, pressure, or heaviness. Acupuncture needles will be retained in the body for 30 minutes. The only difference between two groups will be that, in EA group, participants will receive electro- stimulation between two pairs of acupoints: one pair between LI 10 and LI 12 and the other pair between LI 4 and SJ 5. Electro-stimulation will be applied using electro-acupuncture unit (ES-160) (ITO Physiotherapy and rehabilitation, Japan) which has met the health and safety requirement set by European standard (CE marking) and is widely used in Canadian clinics (distributor ELECTRO-THERAPEUTIC DEVICES INC). Frequency will be set as alternating between 10 and 30Hz (alternating between two frequencies every 3 seconds) and the delivery mode will be set as fast and slow. The pulse width will be set as 400 microseconds. Intensity will be set and maintained at a point at which participants get sensory stimulus, such as tingling or numbness sensation, without visible muscle contraction. Electro-stimulation will be applied for 30 minutes. These stimulation parameters are based on evidence of efficacy in previous laboratory and clinical studies.

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measures as of 27/04/2015:
Pain-free grip strength (PFGS) will be measured with an electronic digital grip dynamometer (MIE Medical research, UK). Participants will be in supine position with the arm adducted, elbow extended, forearm pronated, and wrist extended. For measurements in affected arm, participants will be instructed to apply force gradually on the grip and stop squeezing as soon as pain is provoked; and for measurement in unaffected arm, they will be asked to squeeze the grip maximally.Measurement of affected arm with LE and unaffected arm will be taken at baseline, immediately after the treatment, 24 hours and 72 hours after the treatment. Each measurement will be repeated three times with 30 seconds interval starting with unaffected arm.

Previous primary outcome measures:
Pain-free grip strength (PFGS) will be measured with an electronic digital grip dynamometer (MIE Medical research, UK). Participants will be in supine position with the arm adducted, elbow extended, forearm pronated, and wrist extended. For measurements in affected arm, participants will be instructed to apply force gradually on the grip and stop squeezing as soon as pain is provoked; and for measurement in unaffected arm, they will be asked to squeeze the grip maximally. Measurements of affected arm with LE will be taken at baseline, immediately after an intervention, every 15 minutes for 60 minutes onward, and 24 hours after an intervention; and measurements of unaffected arm will be taken at baseline, immediately after, and 60 minutes after, and 24 hours after an intervention. Each measurement will be repeated three times with 30 seconds interval starting with unaffected arm.

Secondary outcome measures
Current secondary outcome measures as of 27/04/2015:
1. Perceived pain level by participants on the numeric rating scale (NRS). Participants will be provided with a pain diary and be asked to rate their pain level when making a fist with maximal

effort on a scale of 0 to 10. Participants will be asked to position their arm hanging on the side of their body, with their elbow extended, forearm pronated, and wrist extended, when measuring their level of elbow pain. Measurement will be taken at baseline, immediately after the treatment, then 3 times (in the morning after wake up, mid-day, bed-time) a day for 72 hours. The perceived pain level will be also measured at 1st (24 hours after the treatment) and 2nd follow-ups (72 hours later the treatment). Participants will be informed that 0 represents 'no pain at all' and 10 represents 'pain as severe as it could possibly be'.
2. Perceived level of change on the global rating of change (GROC) scale. GROC scale is a reliable and valid measure of patient's perceived level of change in their condition over a period of time; and it is commonly used in clinical research and practice.Participants will be asked "Over the past 24 hours since you received acupuncture treatment, how has your condition changed with respect to your elbow pain?" and be asked to rate on the 7-point Likert type scale, in which seven choices will be given (much better, moderately better, slightly better, unchanged, slightly worse, moderately worse, much worse). We will calculate success rates from the global improvement: we will consider 'much better' and 'moderately better' to be success.

A survey will be implemented in order to find out:
1. Whether the blinding method is successful or not
2. Whether they had to take NSAIDS or any other painkillers for pain control during the study period
3. Whether they had to receive any therapy during the study period
4. Whether they avoided any activities that aggravate their elbow pain

Previous secondary outcome measures:
1. Pressure pain threshold (PPT). Participants will be in supine position with elbow extended and forearm pronated. PPT will be measured at a tender point of the lateral epicondyle of the humerus using a probe of the computerized pressure algometer (Algomed, Medoc Advanced Medical systems, US) at a pressure rate of 40kPa/sec. Participants will be given a patient response unit and be asked to press the button as soon as they feel the onset of pain. PPT will be repeatedly measured until three sequential PPT measurements have a discrepancy of less than 10%. When PPT value stabilizes, PPT at baseline will be recorded. PPT of affected arm will be measured at baseline, immediately after an intervention, and every 15 minutes for 60 minutes onward, and 24 hours after an intervention. PPT of unaffected arm will be measured at baseline, immediately after, and 60 minutes after, and 24 hours after an intervention. Each measurement will be repeated three times with 30 seconds interval starting with unaffected arm.
2. Perceived pain level by participants on the numeric rating scale (NRS). Participants will be provided with a pain diary and be asked to rate their pain level when making a fist with maximal effort on a scale of 0 to 10. Participants will be asked to position their arm hanging on the side of their body, with their elbow extended, forearm pronated, and wrist extended, when measuring their level of elbow pain. Measurement will be taken at baseline, immediately after an intervention, every 15 minutes for 60 minutes onward, then every 4 hours for 72 hours except during sleep hours. Participants will be informed that 0 represents 'no pain at all' and 10 represents 'pain as severe as it could possibly be'.
3. Perceived level of change on the global rating of change (GROC) scale. GROC scale is a reliable and valid measure of patient's perceived level of change in their condition over a period of time; and it is commonly used in clinical research and practice.Participants will be asked "Over the past 24 hours since you received acupuncture treatment, how has your condition changed with respect to your elbow pain?" and be asked to rate on the 5-point Likert type scale, in which five choices will be given such as, much better, slightly better, unchanged, slightly worse, and much worse. We will calculate success rates from the global improvement: we will consider 'much better' to be success.

Overall study start date
01/01/2015

Completion date
28/02/2016

Eligibility

Key inclusion criteria
1. Have had unilateral elbow pain at or around the lateral epicondyle of humerus for longer than six weeks
2. Elbow pain provoked by palpation on the lateral epicondyle of humerus and by gripping
3. Elbow pain triggered by either resisted wrist extension or resisted middle finger extension
4. Aged between 19 and 65 years old

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Have any other concurrent neck, shoulder, elbow, or arm disorders
2. Received injections for lateral epicondylalgia (LE) (e.g. corticosteroid, autologous whole blood, PRP, or prolotherapy)
3. Received acupuncture for LE
4. Pregnant
5. Have pacemakers or other electrical device implanted in the body
6. History of seizures or epilepsy
7. Untreated hemorrhagic disorders
8. Infected tissues, osteomyelitis, or wounds around the elbow
9. Active deep vein thrombosis or thrombophlebitis
10. Impaired sensation at and around the elbow
11. Not able to give accurate and timely feedback due to cognition or communication impairment
12. Cancerous lesions at or around the elbow
13. Who has received a radiation therapy around the elbow within the previous 6 months
14. Impaired circulation around the elbow
15. Surgery or bone fracture at or around the elbow previously
16. Needle phobia
17. Inflammatory rheumatic diseases
18. On opioid medications

Date of first enrolment

01/05/2015

Date of final enrolment
15/12/2015

Locations

Countries of recruitment
Canada

Study participating centre
Centre for Hip Health and Mobility (CHHM)
Vancouver
Canada
-

Sponsor information

Organisation
University of British Columbia

Sponsor details
Rehabilitation Sciences
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212 - 2177 Wesbrook Mall
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Sponsor type
University/education

ROR
https://ror.org/03rmrcq20

Funder(s)

Funder type
Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a relevant peer-reviewed journal within 1 year after completion of final participant.

Intention to publish date
31/12/2016

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	04/08/2017		Yes	No