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Does manipulation therapy relieve pain more rapidly than acupuncture among lateral epicondylalgia?

Submission date
03/02/2016

Recruitment status
No longer recruiting

Registration date
05/02/2016

Overall study status
Completed

Last Edited
10/08/2017

Condition category
Neonatal Diseases

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

Plain English summary of protocol

Background and study aims
Tennis elbow (lateral epicondylalgia) is a condition that results in pain around the outside of the elbow. Sufferers may experience this pain when they bend or lift their arm, when they grip smaller objects (such as a pen) or when twisting the forearm to – for example – turn a doorknob or open a jar. It is caused by overusing the muscles of the elbow. Tennis elbow will eventually get better on its own without treatment, but, for some 20% of cases, symptoms may continue for a year or more. Treatment for the condition often involves a combination of non-pharmacological (drug) therapies. These include corticosteroid injection, iontophoresis, botulinum toxin A, prolotherapy, platelet-rich plasma or autologous blood injection, bracing, physical therapy, shockwave therapy, and laser therapy; however, the results of these treatments remain inconclusive. Manipulation treatment and acupuncture are usually used to lateral epicondulalgia treatment in Traditional Chinese Medicine but there has been little research into comparing how well they perform. This study investigates whether manipulation treatment is beneficial and provides more satisfactory results when compared with acupuncture treatment in patients with lateral epicondylalgia.

Who can participate?
Patients suffering from tennis elbow for longer than 2 months.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 receive manipulation treatment twice a week for two weeks. Those in group 2 receive acupuncture treatment twice a week for two weeks. All participants are assessed in terms of how much pain they experience, how hard they can grip and how well their arm is functioning at various periods throughout the study and for up to eight weeks after treatment.

What are the possible benefits and risks of participating?
Possible risks include light hemorrhage or hematoma for participants in the acupuncture group and some pain (during treatment) for those participants in the manipulation group.

Where is the study run from?
Chang Gung Memorial Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
March 2011 to September 2012

Who is funding the study?
Chang Gung Memorial Hospital (Taiwan)

Who is the main contact?
Dr Hsin-Chia Huang

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Comparison of manipulation treatment with acupuncture treatment in pain relief among lateral epicondylalgia

Study objectives
We hypothesized that pathological tension in the biceps brachii muscle is related to lateral epicondylalgia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Chang-Gung Memorial Foundation, Taipei, Taiwan, ref: IRB No.: 99-1544A3

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled 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
Lateral epicondylalgia

Interventions
Participants were randomly allocated to one of two groups:

1. Manipulation group: participants received radial bone adjustment by being rotated internally the radial bone and extended the biceps brachii muscle simultaneously. The physician performed the manipulation procedure twice in 1 minute with an interval of 30 seconds.
2. Acupuncture group: participants received six acupoints on the forearm, according to a study in Rheumatology published by the Hannover Medical School, Germany. The needle was inserted into the muscle layer and twisted until the de qi sensation was felt. The needle remained in situ for 25 minutes.

Both the manipulation and acupuncture groups received the treatments twice per week for 2 weeks.

Intervention Type
Other

Primary outcome measure
Pain, measured using the pain visual analog scale score (VAS), before treatment in three states, rest, daily activity, and work situations, from the beginning of the study up to 8 weeks following.

Secondary outcome measures

1. Functional impairment, measured by the Disability of Arm, Shoulder, and Hand (DASH) questionnaire, measured at the beginning of treatment as a baseline, the end of treatment, and followed for 2 and 8 weeks after the end of treatment
2. Grip strength (pain- free and maximum), measured using the Jamar hand dynamometer, before treatment in three states, rest, daily activity, and work situations, from the beginning of the study up to 8 weeks following

Overall study start date
22/06/2010

Completion date
30/10/2012

Eligibility

Key inclusion criteria
1. Elbow pain for >2 months
2. Unilateral elbow pain
3. No improvement in the condition despite receiving treatment in previous 4 weeks
4. Visual analog scale(VAS) score> 30

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
35

Key exclusion criteria
Patients who had:
1. Central or peripheral nervous system diseases
2. Radial nerve entrapment
3. Inflammatory rheumatic disease
4. Gout
5. Radiocapitellar osteoarthritis
6. Undergone a operation for tennis elbow
7. Become pregnant

Date of first enrolment
03/03/2011

Date of final enrolment
07/09/2012

Locations

Countries of recruitment
Taiwan

Study participating centre
Chang Gung Memorial Hospital
Taiwan
333

Sponsor information

Organisation
Chang Gung Memorial Hospital (R.O.C)

Sponsor details
No.123, Dinghu Rd
Guishan Township
TAOYUAN
Taiwan
333

Sponsor type
Hospital/treatment centre

Website
https://www.cgmh.org.tw/eng2002/intr_hel.htm

ROR
https://ror.org/02verss31

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Chang Gung Memorial Hospital, Linkou

Alternative Name(s)
Linkou Chang Gung Memorial Hospital

Funding Body Type

Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Taiwan

Results and Publications

Publication and dissemination plan
We would like to publish our result on the “Orthopedic”, “Rehabilitation” or “Complementary and Alternative Medicine” field in early 2016.

Intention to publish date
30/06/2016

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	01/03/2016		Yes	No