







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

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| Submission date 03/02/2016 | Recruitment status No longer recruiting |  Retrospectively registered |
| | |  Protocol not yet added |
| Registration date 05/02/2016 | Overall study status Completed |  SAP not yet added |
| | |  Results added |
| Last Edited 10/08/2017 | Condition category Neonatal Diseases |  Raw data not yet added |
| | |  Study completed |

Plain English Summary

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 epicondylalgia 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
Dr Hsin-Chia Huang

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number
N/A

Study information

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

Study hypothesis
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

Condition

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

Overall study end date

30/10/2012

Eligibility

Participant 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

Participant 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

Recruitment start date

03/03/2011

Recruitment end date

07/09/2012

Locations

Countries of recruitment

Taiwan

Study participating centre

Chang Gung Memorial Hospital

Taiwan

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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 |