

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

Submission date 03/02/2016	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 05/02/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 10/08/2017	Condition category Neonatal Diseases	☐ 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 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
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Additional identifiers

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

Primary study design

Interventional

Study design

Randomized controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

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Sponsor information**Organisation**

Chang Gung Memorial Hospital (R.O.C)

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

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