ISRCTN31227822 https://doi.org/10.1186/ISRCTN31227822

Is there a role for acupuncture in basal thumb arthritis? A randomised controlled trial of real versus sham acupuncture.

Submission date
13/03/2018

Recruitment status
No longer recruiting

Registration date
14/06/2018

Overall study status
Completed

Last Edited
22/07/2021

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis (often referred to as 'wear and tear' arthritis) of the of the thumb base is a common, painful condition which affects 1 in 5 people over the age of 40 years. It affects more women than men and seems to be becoming a more common complaint.
Acupuncture is used for pain relief by many doctors, hand therapists and non-medical practitioners, but it remains a controversial subject in Western medicine. Despite being in use for more than 2000 years, we still cannot decide whether or not it really is effective in painful conditions. From its origins in traditional Chinese medicine, acupuncture has been adapted based on scientific evidence into many areas of Western medical care. This includes pain relief, arthritis care, and end of life care.
While people can find and pay for acupuncture themselves, the NHS has sometimes provided acupuncture in pain clinics, GP practices, and physiotherapy clinics. The National Institute for Health and Care Excellence (NICE) has previously recommended that acupuncture may be considered for lower back pain, tension headache and migraine (NICE, 2009 and 2012), but should not be routinely used in osteoarthritis as there was judged to be insufficient evidence (NICE, 2014).
This study aims to show whether or not acupuncture can help with pain relief for people with thumb base arthritis by comparing a course of real acupuncture for one group of patients to a course of sham (fake) acupuncture for another group of patients. We will look at pain scores and patient's own assessment of daily function before and after treatment to decide if acupuncture is effective.

Who can participate?
Any adult referred to the Pulvertaft Hand Centre with thumb base arthritis between May 2009 and December 2011 will be offered the chance to join the study, provided they have not had acupuncture before for any reason. This is because people who have had acupuncture before are more likely to be able to tell whether they are having real or fake acupuncture, which might affect the results.

What does the study involve?
Participants will first be asked some questions to make sure it is safe for them to join the study. If this is OK then they will fill out a questionnaire about their hand problems and have an assessment of hand function with a therapist. Participants will be allocated at random to have a course of either real or fake acupuncture. This involves six visits to hospital over three weeks for acupuncture treatment. Acupuncture treatment involves sitting on a treatment couch and having some small needles inserted around the painful hand and wrist for between 15 and 20 minutes. After treatment, a questionnaire will be filled out and a therapist will assess hand function again. Questionnaires will also be sent fortnightly in the post for a maximum of 3 months to assess hand function. Participants and the assessors will not be told which treatment has been given as this improves the chances of getting accurate results.

What are the possible benefits and risks of participating?
The possible benefits are pain relief in the affected thumb. This can last for several weeks or months in some people. The possible risks from having needles inserted into the skin include a small amount of bleeding or bruising, an increase in pain, a minor injury to a nerve, or infection. None of these risks is common. Some people can feel faint, dizzy or sleepy during or after acupuncture.

Where is the study run from?
The Pulvertaft Hand Centre, part of the Royal Derby Hospital.

When is the study starting and how long is it expected to run for?
The study started recruiting in May 2009 and finished in December 2012.

Who is funding the study?
The Pulvertaft Hand Centre Charitable Fund.

Who is the main contact?
1. Mrs Victoria Jansen, Senior Hand and Research Physiotherapist, Pulvertaft Hand Centre
Tel: 01332 787493, email: Victoria.jansen@nhs.net
2. Miss Anna Barnard, Consultant Hand / Plastic Surgeon, email: anna.barnard4@nhs.net

Contact information

Type(s)
Scientific

Contact name
Mrs Victoria Jansen

ORCID ID
http://orcid.org/0000-0002-0700-7462

Contact details
Pulvertaft Hand Centre, Royal Derby Hospital
Kings Treatment Centre (KTC) Level 2
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DHRD/2009/008

Study information

Scientific Title
A single-blind randomised controlled trial assessing pain relief following real or sham acupuncture in adults with symptomatic thumb carpometacarpal joint arthritis.

Study objectives
Real acupuncture provides greater pain relief than sham acupuncture in adults with thumb carpometacarpal joint arthritis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Derbyshire Research Ethics Committee, 24/03/2009, 09/H0401/24

Study design
Single-blinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Osteoarthritis of the thumb carpometacarpal joint

Interventions

Patients were allocated blind in order of recruitment according to a randomisation list (nQuery Advisor v6.01 software, mixed block-size randomisation sequence) to either acupuncture (treatment arm, penetrating needle) or sham acupuncture (placebo, non-penetrating needle). Both treatment and sham patients received six treatment sessions over 3 weeks with Gauge 8 solid Streitberger TM (asia-med, Germany) acupuncture needles using standardised acupuncture needle locations and durations.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain relief was assessed using visual analogue pain scores (VAS) during an objective assessment of range of motion and strength, at pre-treatment and 1 week post-treatment.

Secondary outcome measures
1. Measurements of motion were taken using a standardised protocol (Adams, Greene and Topoozian, 1992) and strength was measured using Jamar grip and pinch meters, both valid reliable and accurate assessment tools (Mathiowetz et al, 1984).
2. Patient rated functional outcome was measured by the pre- and 1 week post-treatment scores using the Nelson Hospital questionnaire (NHQ) (Citron et al, 2007).
3. The duration of any improvement was assessed by patients completing the NHQ again by post or telephone at 2-weekly intervals post treatment until either 12 weeks had passed or their score had returned to the pre-treatment baseline.
4. Each patient's perceived acupuncture experience was assessed by recording their pre-treatment expectations, their needling sensations, and by recording their post-treatment opinions of acupuncture. The Southampton Needling Questionnaire (White et al, 2008) is designed to assess the quality of needling by recording desirable and undesirable sensations and was used after first and last treatments.

Overall study start date
01/09/2008

Completion date
05/07/2011

Eligibility

Key inclusion criteria
1. Acupuncture-naïve
2. Newly referred to either surgical or therapist clinics at the Pulvertaft Hand Centre (PHC) with osteoarthritis of the basal thumb joint
3. Where both hands were affected, the worst affected hand according to the Nelson Hospital Questionnaire (NHQ) score was treated

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Total final enrolment
70

Key exclusion criteria
1. Prior experience of acupuncture
2. Previous surgery to the affected thumb
3. Steroid injection to the affected joint within 12 months
4. Change in treatment to the affected thumb within 6 weeks e.g. splint/exercise regime, or ongoing changes in symptoms following such a change
5. Contraindication to acupuncture: warfarin with unstable INR, epilepsy, pregnancy, needle phobia, unstable cardiac condition or hypertension, prosthetic heart valve, vascular or neuropathic problem at the proposed site of needling
6. Inability to understand written and spoken English, or to give informed consent

Date of first enrolment
23/06/2009

Date of final enrolment
05/07/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Pulvertaft Hand Centre
Royal Derby Hospital
Kings Treatment Centre (KTC) Level 2
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Sponsor information

Organisation

Derby Teaching Hospitals NHS Foundation Trust

Sponsor details
Research and Development,
Royal Derby Hospital
Uttoxeter Road
Derby
England
United Kingdom
DE22 3NE

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Not defined

Funder Name
Derby Hand Charity

Results and Publications

Publication and dissemination plan

Intention to publish date
01/06/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as consent for data sharing was not obtained.

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		01/06/2020	06/05/2021	Yes	No