

An open pilot trial of the effects of acupuncture in the treatment of knee osteoarthritis.

Submission date 30/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 30/09/2005	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 04/06/2009	Condition category Musculoskeletal Diseases	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0265041788

Study information

Scientific Title

Study objectives

In an open study, can acupuncture be shown to have an analgesic effect for patients with osteoarthritis of the knee?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Musculoskeletal Diseases: Knee osteoarthritis

Interventions

Open pilot study looking at patients who have osteoarthritis of their knee and whose pain is not well-controlled on conventional treatment. The patients would be asked to take part for a period of 5 weeks. Possible patients must be over 18 years of age, not women of child-bearing age, not patients with pacemakers fitted. Patients will be randomised into one of three groups:

1. Patients receiving acupuncture alone
2. Patients receiving acupuncture as well as their conventional therapy
3. Patients continuing on their conventional therapy

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Patients Global Assessment of Efficacy
2. Investigator Global Assessment of Efficacy
3. 100m Visual Analogue Scale for Pain Assessment
4. WOMAC Index
5. Kellgren & Lawrence Scale for radiological assessment of osteoarthritis

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/01/2007

Eligibility**Key inclusion criteria**

This is a pilot study - the size of any effect not known. Volunteers will be recruited from the rheumatology outpatients clinics at Selly Oak Hospital. We anticipate about 10 patients per group will be sufficient to enable a power calculation to be made. They must have osteoarthritis of the knee, and find that their pain is not well controlled by conventional medicine. They must be over 18 years of age.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

Key exclusion criteria

Patients will be excluded if they have any of the following: rheumatoid arthritis, Gout, psoriatic arthritis, osteoarthritis of the hip, patients with pacemakers fitted, patients with known metal allergies, patients with an history of prosthetic or damaged valves, patients with hemophilia, patients taking an anticoagulant or oral corticosteroid, patients suffering with dementia or other psychiatric disease, patients with Grade I or IV on the Kellgren & Lawrence scale, patients with uncontrolled diabetes and patients with a skin disease likely to affect the use of the acupuncture needles.

Date of first enrolment

01/07/2003

Date of final enrolment

01/01/2007

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Rheumatology

Birmingham

United Kingdom

B29 6JD

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

University Hospital Birmingham NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2004		Yes	No