ISRCTN22366060 https://doi.org/10.1186/ISRCTN22366060

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 04/06/2009	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr RW Jubb

Contact details
Rheumatology
Selly Oak Hospital
Birmingham
United Kingdom
B29 6JD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Single-centre

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
30

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
England

United Kingdom

Study participating centre
Rheumatology
Birmingham
United Kingdom
B29 6JD

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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