

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

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/06/2009	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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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?
<a href="#">Results article</a>	results	01/03/2004		Yes	No