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The process of acupuncture: a randomised controlled trial and qualitative study to evaluate the relative contributions of specific and non-specific effects

Submission date
31/01/2006

Recruitment status
No longer recruiting

Registration date
03/03/2006

Overall study status
Completed

Last Edited
20/07/2010

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
170/03/t

Study information

Scientific Title

Study objectives
1. Acupuncture is superior to placebo for the treatment of Osteo-Arthritic (OA) hip or knee
2. Empathic approach to treatment yields superior efficacy than a non-empathic approach
3. A needle-type placebo has a greater effect than a non-needle placebo

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Southampton and South West Hampshire Local Research Ethics Committee (LREC) approved on the 21st of August 2003 (ref: 170/03/t)

Study design
Randomised single blind placebo controlled multi-factorial trial with a nested qualitative study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Osteoarthritis (OA)

Interventions
Patients are randomised to receive one of the following interventions:
1. Acupuncture which involves a course of treatment using a standardised but flexible choice of acupuncture points around the affected area and at distal points
2. Placebo acupuncture which involves using non-penetrating needles
3. Acupuncture-type treatment is also a placebo treatment and involves the use of a pseudo-electrical stimulation to acupuncture points via surface skin electrodes

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Pain measured on a VAS

Secondary outcome measures
1. Western Ontario and McMaster (WOMAC) University Osteoarthritis Index functional score
2. Nottingham Health profile

Overall study start date
01/09/2003

Completion date
01/09/2007

Eligibility

Key inclusion criteria
1. Subjects aged between 18 and 80
2. Chronic or stable pain, predominantly from a single joint (hip or knee) of known mechanical aetiology i.e. osteo-arthritis
3. Score an average of 30 or more on the 100 mm visual analogue scale (VAS) in the pre-randomisation phase of the study
4. Not be on any active treatment (e.g. physiotherapy or homeopathy)
5. Ability to attend clinic twice a week for the duration of treatment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
288

Key exclusion criteria
1. Pregnancy
2. Suffering serious co-morbidity (including severe back pain)
3. Prolonged or current steroid use
4. Waiting for hip/knee revision
5. Patients with needle phobia or allergy to sticking plaster

Date of first enrolment

01/09/2003

Date of final enrolment
01/09/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Health Professions
Southampton
United Kingdom
SO17 1BJ

Sponsor information

Organisation
University of Southampton (UK)

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Sponsor type
University/education

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
Department of Health (UK) - Funded Trials for Complementary Alternative Medicine (CAM) (ref: 03/12)

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	30/04/2010		Yes	No