ISRCTN83933522 https://doi.org/10.1186/ISRCTN83933522

A Randomised Controlled Trial (RCT) on Acupuncture Safety/Efficacy in Knee Osteoarthritis

Submission date
14/07/2004

Recruitment status
No longer recruiting

Registration date
19/10/2004

Overall study status
Completed

Last Edited
18/08/2009

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

ClinicalTrials.gov (NCT)
NCT00010946

Protocol serial number
UO1 AT 00171

Study information

Scientific Title

Study objectives
Added 18/08/09:
The goal of this research is to determine the efficacy and safety of Traditional Chinese Acupuncture (TCA) in patients with osteoarthritis of the knee. A three arm randomised controlled trial (RCT) using sham TCA, true TCA, and an education/attention comparison group is proposed. The primary hypothesis to be tested is that patients randomised to true TCA will have significantly more improvement in pain and function as measured by the Womac Pain & Function Scales and patient global assessments than patients randomised to the sham acupuncture and education/attention control groups.

As of 18/08/09 this record has been updated. All updates can be found under the relavent field with the above update date.

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)
Treatment

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

Interventions
Patients are randomised to one of three intervention groups:
1. Real Acupuncture
2. Sham Acupuncture
3. Health Education

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Added 18/08/09:
Improvement in pain and function as measured by the Womac Pain & Function Scales and patient global assessments

Key secondary outcome(s))
Added 18/08/09:
1. Determine if improvement with TCA differs between patients below age 65 vs. those aged 65 and above,
2. Determine if improvement with TCA differs by racial/ethnic group (ie., Caucasian, Black, Hispanic), and
3. Determine if improvement with TCA differs by stage of radiographic severity of knee OA at baseline (KL grade 2, 3 or 4)

Completion date
31/08/2003

Eligibility

Key inclusion criteria
1. 570 Males and Females aged 50 and older
2. Diagnosis of osteoarthritis of the knee (fulfilling American College of Rheumatology [ACR] criteria) for at least 6 months duration
3. At least moderate pain in the knee for most days in the last month
4. Must be taking analgesic or nonsteroidal anti-inflammatory agents for control of pain
5. Documented radiographic changes of osteoarthritis - presence of osteophyte - at the time of rheumatological screening
6. Signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/09/1998

Date of final enrolment
31/08/2003

Locations

Countries of recruitment
United States of America

Study participating centre
2200 Kernan Drive
Baltimore, Maryland
United States of America
21207

Sponsor information

Organisation
National Center for Complementary + Alternative Medicine (NCCAM), NI of Arthritis + Musculoskeletal + Skin Diseases (NIAMS)

ROR
https://ror.org/00190t495

Funder(s)

Funder type
Research organisation

Funder Name
National Center for Complementary and Alternative Medicine (NCCAM)

Alternative Name(s)
NCCAM

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Funder Name
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

Alternative Name(s)

The National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH/National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Arthritis & Musculoskeletal & Skin Diseases, Instituto Nacional de Artritis y Enfermedades Musculoesqueléticas y de la Piel, NIAMS

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
United States of America

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	01/12/2006		Yes	No