

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

Submission date 14/07/2004	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 19/10/2004	Overall study status Completed	☐ Protocol
Last Edited 18/08/2009	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☒ 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 relevant field with the above update date.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

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