A randomised, single-blind, two-limbed, parallelgroup study to compare the effectiveness of 'individualised traditional Korean acupuncture' with one of 'standardised acupuncture' in Korean patients with knee osteoarthritis

Submission date	Recruitment status No longer recruiting	Prospectively registered		
27/10/2006		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
16/01/2007	Completed Condition category	☐ Results		
Last Edited		Individual participant data		
14/01/2021	Musculoskeletal Diseases	Record updated in last yea		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SR-2

Study information

Scientific Title

A randomised, single-blind, two-limbed, parallel-group study to compare the effectiveness of 'individualised traditional Korean acupuncture' with one of 'standardised acupuncture' in Korean patients with knee osteoarthritis

Acronym

The effectiveness of Individualised Acupuncture for Knee Osteoarthritis

Study objectives

To determine whether individualised acupuncture provides greater pain relief compared with standardised acupuncture in patients with OsteoArthritis (OA) of the knee.

Ethics approval required

Old ethics approval format

Ethics approval(s)

This trial was approved by an ethics board of Dongguk International Hospital on 23rd May 2006.

Study design

Two-armed, single blinded, randomided, controlled trial.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Knee Osteoarthritis

Interventions

Arm A: Individualised traditional Korean acupuncture

Arm B: Standardised acupuncture

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Pain rating based on a 100 mm VAS

Secondary outcome measures

- 1. Western Ontario MacMaster Questionnaire (WOMAC) Scale
- 2. Quality of Life (Short Form health survey [SF-36])
- 3. Leguesne Functional Index (LFI) score
- 4. Physical function was evaluated by the Korean version of Health Assessment Questionnaire (KHAQ)

Overall study start date

01/05/2006

Completion date

01/02/2007

Eligibility

Key inclusion criteria

- 1. At least 40 years old
- 2. Current symptoms of chronic (six months), stable pain and/or stiffness in one or both knees during weight-bearing activities
- 3. Knee pain due to OA rated more than 4 cm on a 10 cm Visual Analogue Scale (VAS) in one or both knees
- 4. Morning stiffness of knee for less than or equal to 30 minutes
- 5. Mild joint space narrowing (more than or equal to 2 mm remaining) in knee AnteroPosterior (AP) standing or Rosenberg view

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

50

Key exclusion criteria

- 1. Inflammatory, metabolic, or neuropathic arthropathies
- 2. Trauma or surgery to the knee(s) which is causing pain or functional problems within six months prior to the enrolment period
- 3. Suspicious meniscus injury by physical examination

- 4. Pain emanating more from back or hip than from knee, interfering with patient knee assessment
- 5. Any condition which severely limits local ambulation, such as amputation or stroke
- 6. History of or evidence of active rheumatologic disease, severe peripheral neuropathy, clinically evident cardiac or respiratory disease that interferes with functional status, or other serious diseases, including psychiatric disorders
- 7. Autoimmune disease, Systemic Lupus Erythematosus (SLE), psoriatic arthritis, active (redness, swelling, fever, etc.) gout or pseudo-gout within six months prior to screening
- 8. History of prolotherapy, or injection of hyaluronic acid or cortisone within the last three months
- 9. Inability to stop anti-inflammatory medication or Non Steroidal Anti-Inflammatory Drug (NSAID) such as acetaminophen for the entire study
- 10. Bleeding disorders that might contraindicate acupuncture
- 11. Pension or disability benefits

Date of first enrolment 01/05/2006

Date of final enrolment 01/02/2007

Locations

Countries of recruitment

Korea, South

Study participating centre

Department of Acupuncture and Moxibustion
Goyang-si,Gyeonggi-do
Korea, South
411-773

Sponsor information

Organisation

Korea Institute of Oriental Medicine (South Korea)

Sponsor details

461-24, Jeonmin-dong Yuseong-gu Daejeon Korea, South 305-811

Sponsor type

Research organisation

Website

http://www.kiom.re.kr/english/

ROR

https://ror.org/005rpmt10

Funder(s)

Funder type

Research organisation

Funder Name

Korea Institute of Oriental Medicine (South Korea)

Alternative Name(s)

KIOM

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Korea, South

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?
Protocol article	protocol	30/12/2006	14/01/2021	Yes	No