

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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, randomised, controlled trial.

Primary study design

Interventional

Study type(s)

Treatment

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(s)

Pain rating based on a 100 mm VAS

Key secondary outcome(s)

1. Western Ontario MacMaster Questionnaire (WOMAC) Scale
2. Quality of Life (Short Form health survey [SF-36])

3. Lequesne Functional Index (LFI) score

4. Physical function was evaluated by the Korean version of Health Assessment Questionnaire (KHAQ)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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)

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

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