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

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. Lequesne 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