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The effect of infrared heating or traditional moxibustion in osteoarthritis of the knee

Submission date
25/12/2020

Recruitment status
No longer recruiting

Registration date
05/01/2021

Overall study status
Completed

Last Edited
16/07/2021

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Osteoarthritis, a common joint disorder, is the most common form of arthritis in the world. The knee joint is the most common site affected by osteoarthritis. Joint pain caused by knee osteoarthritis can severely reduce the patient's quality of life. Based on previous research, traditional moxibustion and laser moxibustion could relieve pain effectively and improve function in patients.
Moxibustion is a type of traditional Chinese medicine. It involves burning moxa, a cone or stick made of ground mugwort leaves, on or near your body's meridians and acupuncture points.
The aim of this study is to compare the effects of laser moxibustion and traditional moxibustion on knee pain in osteoarthritis.

Who can participate?
Patients aged 50 to 75 undergoing conventional knee osteoarthritis treatment

What does the study involve?
Participants are randomly allocated to be treated with either CO2 laser moxibustion or traditional moxibustion at the acupoints on the affected knee(s). Patients in both groups receive 20 minutes of treatment, three times per week for 4 weeks. The effects of treatment are assessed through questionnaires at the start of the study and at 2, 4, 8, 12 and 24 weeks after they join the study. The assessments will take place at either Tongren Hospital or Shanghai Pudong Hospital except for the assessment at 24 weeks, where the questionnaire will be mailed to participants.

What are the possible benefits and risks of participating?
CO2 laser moxibustion and traditional moxibustion can reduce pain and improve knee joint stiffness and function in patients with knee osteoarthritis. Some patients might have local skin flushing or blistering (not instantly, but usually one day after treatment) at the site of treatment. Usually, the blister is naturally absorbed within a day or two without obvious scarring of the skin.

Where is the study run from?
1. Tongren Hospital Affiliated to Shanghai Jiaotong University (China)
2. Shanghai Pudong Hospital of Traditional Chinese Medicine (China)

When is the study starting and how long is it expected to run for?
June 2019 to May 2021

Who is funding the study?
Shanghai Key Laboratory of acupuncture mechanism and acupoint function (China)

Who is the main contact?
Prof. Xueyong Shen
sxy1@shutcm.edu.cn

Contact information

Type(s)
Public

Contact name
Miss Jing Fang

Contact details
Shanghai Key Laboratory of Acupuncture Mechanism and Acupoint Function
Shanghai University of Traditional Chinese Medicine
1200 Cailun Road
shanghai
China
201203
+86 18816511872
sxy1@shutcm.edu.cn

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The efficacy of moxibustion and infrared laser moxibustion in knee osteoarthritis: A randomized non-inferiority study

Acronym
EILMK

Study objectives
A 4-week CO2 infrared laser moxibustion will reduce pain and improve knee joint stiffness and function among patients with knee osteoarthritis as compared with traditional moxibustion treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/07/2019, Institutional Review Board (IRB) of Tongren Hospital Affiliated to Shanghai Jiaotong University (Room 309, Building 6-3, 1111 Xianxia Road, Changning District, Shanghai, China, 201103; +86 (021) 52039999-96341; no email provided), ref: 2019-022-02

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
Patients with knee osteoarthritis are randomly allocated into either CO2 laser moxibustion or traditional moxibustion groups.

Patients will receive CO2 laser moxibustion or traditional moxibustion treatment on ST35, EX-LE4 and Ashi points in the area of the affected knee(s). Patients in both groups receive 20 minutes of treatment, 3 times per week for 4 weeks.

The effects of treatment on the most painful joint (which is identified through participant report at baseline and is the joint assessed throughout the study) are assessed at the hospital at

baseline, 2 (mid-term), 4 (the end of treatment), 8, and 12 weeks after baseline. During the follow-up period (5 to 24 weeks), the subject report on adverse events and side effects will be sought via telephone call weekly.

Participants will be allowed to take any analgesic or non-steroidal anti-inflammatory drugs that they used before the study. They will be asked to record the daily dose during the entire clinical trial, and then the investigators will analyze the changes in the dose.

Laser moxibustion: The wavelength of laser irradiation was 10.6 μm, and the output power was adjusted in the range of 160-180 mW. Energy density ranged from 61.2 to 68.8 J/cm2 for one treatment.

Traditional moxibustionWe used a commercially available moxibustion device (Nanyang Hanyi Moxa Company, Ltd., Nanyang, Henan, China). It has a cylindrical opening to hold a pillar of moxa; at its base is an adhesive membrane. During treatment, the device is placed at an acupoint, and the moxa is burned about 8 mm above the skin.

Both groups have 20 minutes of treatment.

Intervention Type
Other

Primary outcome measure
Knee pain, measured using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain score at baseline and 2, 4, 8, 12, and 24 weeks

Secondary outcome measures
1. Knee function measured using the WOMAC function score at baseline, weeks 2, 4, 8, 12, and 24 weeks
2. Knee stiffness measured using the WOMAC stiffness score at baseline, weeks 2, 4, 8, 12, and 24 weeks
3.Knee osteoarthritis symptoms measured using the WOMAC total score at baseline, weeks 2, 4, 8, 12, and 24 weeks
4. Knee pain measured using the Visual Analogue Scale (VAS) pain score at baseline, weeks 2,4, 8, 12, and 24 weeks
5. The 50-yard walking time was assessed and recorded among the participants at baseline, weeks 4 and 12weeks to observe improvements in walking.
6. Quality of life measured using the 36-Item Short Form Health Survey (SF-36) at 4, 12 and 24 weeks and the Quality of Life Scale (QOLS) at 4 weeks
7. Participant perception of the safety of the treatment measured by investigator question (with possible answers of: safe, less safe, safety problem, or serious safety problem) at 4 weeks

Overall study start date
01/06/2019

Completion date
01/05/2021

Eligibility

Key inclusion criteria

Patients aged 50 to 75 undergoing conventional knee osteoarthritis treatment

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
92

Total final enrolment
92

Key exclusion criteria
1. Knee pain caused by other diseases (such as rheumatoid arthritis, fibromyalgia syndrome, chronic fatigue syndrome, and ankylosing spondylitis)
2. Treatment with steroid drugs in the past 3 months
3. Received acupuncture or moxibustion treatment in the past 3 months
4. Intra-articular injection of hyaluronate in the past 6 months
5. Joint puncture or arthroscopy in the past year
6. Previous (or planned for during the trial) knee or hip replacement surgery
7. Use of other topical treatments for osteoarthritis of the knee
8. Diagnosis of any serious diseases including, but not limited to, heart disease, lung disease, kidney disease, liver disease, malignant tumor, systemic infection, infectious disease, and/or mental illness
9. Participation in another clinical study in the past month

Date of first enrolment
15/07/2019

Date of final enrolment
01/01/2021

Locations

Countries of recruitment
China

Study participating centre
Tongren Hospital Affiliated to Shanghai Jiaotong University
No.1111 Xianxia Road Changning District
Shanghai
China
200336

Study participating centre
Shanghai Pudong Hospital of Traditional Chinese Medicine
No. 399 Pingchuan Road Pudong New District
Shanghai
China
201200

Sponsor information

Organisation
Shanghai University of Traditional Chinese Medicine

Sponsor details
1200 Cailun Road
Pudong new district
Shanghai
China
201203
+86 (0)21 51322042
kyctcm@vip.sina.com

Sponsor type
University/education

Website
http://www.shutcm.edu.cn/web/guest/index

ROR
https://ror.org/00z27jk27

Funder(s)

Funder type
University/education

Funder Name
Shanghai University of Traditional Chinese Medicine

Alternative Name(s)
Shanghai University of TCM, SHUTCM

Funding Body Type

Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Publication and dissemination plan
A study is planned for publication in a medical journal.

Intention to publish date
01/05/2022

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/07/2021	16/07/2021	Yes	No