ISRCTN21174552 https://doi.org/10.1186/ISRCTN21174552

The efficacy of jade moxibustion in knee osteoarthritis

Submission date
21/02/2020

Recruitment status
No longer recruiting

Registration date
28/02/2020

Overall study status
Completed

Last Edited
05/06/2024

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] 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. The aim of this study is to compare the effects of jade 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 jade 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?
Jade 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?
May 2019 to June 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)
Scientific

Contact name
Mr Xueyong Shen

Contact details
Shanghai University of Traditional Chinese Medicine
1200 Cailun Road
Pudong New District
Shanghai
China
201203
+86 2151322175
sxy1@shutcm.edu.cn

Type(s)
Public

Contact name
Mr Lusheng Chen

ORCID ID
http://orcid.org/0000-0001-9618-3080

Contact details
Shanghai University of Traditional Chinese Medicine
1200 Cailun Road
Pudong District
Shanghai
China
201203
+86 13681913509
13681913509@163.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Comparison of the efficacy of jade moxibustion and traditional moxibustion in knee osteoarthritis: a pilot randomized clinical trial

Study objectives
A 4-week jade moxibustion treatment regimen will reduce pain among patients with knee osteoarthritis as compared with traditional moxibustion treatment, and the therapeutic effect might be related to the cytokines such as Interleukin in serum.

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), ref: 2019-022-02

Study design
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 jade moxibustion or traditional moxibustion groups.

Patients will receive jade moxibustion or traditional moxibustion treatment on ST35, ST34, EX-LE4, SP10 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. At 24 weeks, the questionnaire will be mailed to the subjects and they will be asked to post them back after filling them out.

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.

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. Sensation measured by investigator question "What do you feel during the treatment?" (with possible answers of: heat, cold, pain, no feeling, or other which will be described)
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
8. Dose of analgesic or non-steroidal anti-inflammatory drugs consumed, determined through daily participant reports from baseline to 24 weeks
9. Any adverse events or side effects during the study are determined from the subject and investigator reports collected weekly from baseline to 24 weeks. Common side effects include redness and blisters by jade moxibustion and traditional moxibustion. Serious adverse events will also be reported to the Ethics Committee

Overall study start date
01/05/2019

Completion date

30/06/2021

Eligibility

Key inclusion criteria
1. Aged 50 to 75 years
2. Knee osteoarthritis according to the American College of Rheumatology Diagnostic Criteria
3. Radiologic confirmation of knee osteoarthritis (Kallgren-Lawrence level ≥1)
4. Moderate to severe knee pain on most days of the past month (VAS score for arthritic pain ≥40)
5. Has a full understanding and gives informed consent to participate in the study

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
148

Total final enrolment
94

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
10/07/2019

Date of final enrolment
31/12/2020

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
Industry

Funder Name
Shanghai Key Laboratory of Acupuncture Mechanism and Acupoint Function

Alternative Name(s)
SKLAA

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
China

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed medical journal and planned presentations at local and international conferences.

Intention to publish date
30/04/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Xueyong Shen (sxy1@shutcm.edu.cn) or Dr Lusheng Chen (13681913509@163.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/04/2020	27/04/2020	Yes	No
Results article		04/06/2023	05/06/2024	Yes	No