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Effects of moxibustion on patients with knee osteoarthritis

Submission date
03/04/2014

Recruitment status
No longer recruiting

Registration date
24/04/2014

Overall study status
Completed

Last Edited
17/12/2020

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 patients quality of life. The purpose of this study is to observe whether the traditional Chinese medicinal therapy moxibustion provides greater relief from pain and joint stiffness and improved function.

Who can participate?
Patients aged 45 years or older, male or female, undergoing conventional knee osteoarthritis treatment.

What does the study involve?
Patients were randomly allocated to receive either real or sham moxibustion. Patients in both groups received 20 minutes of treatment, three times per week for 6 weeks. The effects of treatment were assessed at the start of the study and after 3 weeks, 6 weeks (the end of treatment), 12 weeks and 24 weeks.

What are the possible benefits and risks of participating?
Moxibustion can reduce pain and improve knee joint stiffness and function in patients with knee osteoarthritis. Some patients have had local skin flushing or blistering (not instantly, but usually 1 day after treatment) at the site of treatment. Usually the blister was naturally absorbed within 3 days without obvious scarring on the skin.

Where is the study run from?
Traditional Chinese Medicine Hospital of Pudong New District, Shanghai, China; the Community Service Center of Chuansha, Pudong, Shanghai, China; and the Nantong University's affiliated hospital, Nantong, China.

When is the study starting and how long is it expected to run for?
The study started in August 2009 and recruitment ended in November 2011.

Who is funding the study?
National Basic Research Program of China, National Natural Science Foundation of China, The Key Program of State Administration of Traditional Chinese Medicine of China, and the Shanghai Municipal Science Foundation.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ChiCTR-TRC-11001408

Study information

Scientific Title
Effectiveness of moxibustion treatment as adjunctive therapy in osteoarthritis of the knee: a randomized, double-blinded, placebo-controlled clinical trial

Study objectives
The hypothesis is that the moxibustion can reduce pain and improve knee joint stiffness, function, and quality of life in patients with knee osteoarthritis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethic Review Committee of Chinese Clinical Trials Registry, 28/06/2011, ChiECRCT-20110022

Study design
Multi-centre double-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

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

Interventions
Patients with knee osteoarthritis were randomly divided into real and sham moxibustion groups. Patients received moxibustion and sham moxibustion treatment on Dubi (ST-35), EX-LE4, and an Ashi point in the area of the affected knee(s). Three consecutive moxa pillars were burned at each point. Once the device was affixed at a point, the first pillar was lit. After burning, the residual pillar was removed and another pillar was inserted and
burned. A pillar burns for about 6 min, making the moxibustion session about 20 min long. Patients in both groups received 20 minutes of treatment, three times per week for 6 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
WOMAC (VAS3.1) Questionnaire was applied to assess the therapeutic effects in terms of joint pain, stiffness, and functional disorder of the participants at 3 weeks and 6 weeks after the treatment initiation, and the long-term effects were also assessed at 12, and 24 weeks after baseline

Secondary outcome measures
1. Short Form 36 (SF-36) component scales were used to assess health-related quality of life at baseline, week 3, week 6 and week 12

2. The 50-yard walking time was assessed and recorded at baseline and week 6 to observe the improvement in walking

Overall study start date
01/08/2009

Completion date
30/04/2012

Eligibility

Key inclusion criteria
1. Male or female, 45 or older, with knee osteoarthritis diagnosed according to American College of Rheumatology criteria, including radiographic evidence of at least one osteophyte at the tibiofemoral joint in one or both knees (KellgrenLawrence score 2 or 3)
2. Pain score of at least 3 points on a 10-point visual analogue scale for most days during the previous month
3. Willingness to sign the consent form and be randomly assigned into either a treatment or a placebo group

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
110

Key exclusion criteria
1. Presence of serious medical conditions that preclude participation in the study
2. Intra-articular corticosteroid or hyaluronate injections, knee surgery, or use of topical capsaicin cream during the preceding 6 months
3. Previous experience with moxibustion
4. Planned events such as knee replacement that would interfere with participation in all 24 weeks of the study

Date of first enrolment
01/08/2009

Date of final enrolment
01/11/2011

Locations

Countries of recruitment
China

Study participating centre
1200 Cailun Road
Shanghai
China
201023

Sponsor information

Organisation
Shanghai University of Traditional Chinese Medicine (China)

Sponsor details
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Sponsor type
University/education

Website
http://www.csc.edu.cn/laihua/universitydetailen.aspx?collegeId=194

ROR
https://ror.org/00z27jk27

Funder(s)

Funder type
Government

Funder Name
National Basic Research Program of China (2009CB522901)

Funder Name
National Natural Science Foundation of China (81320108028, 81202648)

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
The Key Program of State Administration of Traditional Chinese Medicine of China (ZYSNXD-CC-ZDXK-07)

Funder Name
The Shanghai Municipal Science Foundation

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?
Results article	results	24/06/2014		Yes	No
Results article	results	01/06/2015		Yes	No
Results article	results	01/06/2020	17/12/2020	Yes	No