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Effects of CO2 infrared laser moxibustion on patients with knee osteoarthritis

Submission date
22/08/2013

Recruitment status
No longer recruiting

Registration date
06/09/2013

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 in the oriental population. Joint pain caused by knee osteoarthritis can severely impair the patients quality of life. The purpose of this study is to observe whether a Chinese medicinal therapy, infrared laser moxibustion, provides greater relief from pain and joint stiffness and improved function.

Who can participate?
Patients aged 50 years or older, male or female, undergoing knee osteoarthritis treatment can participate in the study.

What does the study involve?
Patients with knee osteoarthritis were randomly divided into real and sham laser moxibustion groups. Patients received 10.6 μm infrared laser moxibustion and sham laser moxibustion treatment. Patients in both groups received 20 minutes of treatment, three times per week for 4 weeks. The effects of treatment were assessed before, mid-term (after 2 weeks), at the end (after 4 weeks) and 4 weeks post-treatment termination. Time taken to walk 50 yards was also calculated.

What are the possible benefits and risks of participating?
Infrared laser 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 one day after treatment) at the site of irradiation. Usually the blister was naturally absorbed within a day or two without obvious scarring of the skin.

Where is the study run from?
Longbai Community Health Service Center in Shanghai Minhang District, China.

When is the study starting and how long is it expected to run for?
The study started in August 2010 and recruitment ended in July 2011.

Who is funding the study?
The study was supported by:
1. National Basic Research Program of China
2. National Natural Science Foundation of China
3. The Key Program of State Administration of Traditional Chinese Medicine of China
4. 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-12002338

Study information

Scientific Title
Effects of CO2 infrared laser moxibustion on patients with knee osteoarthritis: a double-blind, randomized, controlled study

Study objectives
The hypothesis is that the CO2 infrared laser moxibustion can reduce pain and improve knee joint stiffness and function in patients with knee osteoarthritis.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Institutional Review Board of Shuguang Hospital Affiliated Shanghai University of Traditional Chinese Medicine.
The study was approved on 14 June 2007.

Study design
Single-centred 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
Patients with knee osteoarthritis

Interventions
Patients with knee osteoarthritis were randomly divided into real and sham laser moxibustion groups. Patients received 10.6 μm infrared laser moxibustion and sham laser moxibustion treatment on Dubi (ST-35) leg acupoint symmetrically. Patients in both groups received 20 minutes of treatment, three times per week for 4 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 after 2 weeks and 4 weeks of the treatment initiation, and the long-term effects were also assessed 4 weeks post-treatment.

Secondary outcome measures
The 50-yard walking time was assessed and recorded among the participants after 2 weeks and 4 weeks of the treatment as well as 4 weeks post-treatment to observe improvements in walking. In the follow-up, we asked the participants to assess their therapeutic effects and guess their group assignment to assess the masking effectiveness of the trial. Additionally, the participants would also be asked whether they thought the treatment were safe.

Overall study start date

01/08/2010

Completion date
31/07/2011

Eligibility

Key inclusion criteria
1. Middle-aged and aged individuals, aged 50 years or older, male or female
2. According to the knee OA diagnostic criteria of the American College of Rheumatology, radiographic evidence of at least 1 osteophyte at the tibiofemoral joint (KellgrenLawrence grade II or III)
3. Moderate or greater clinically significant knee pain on most days during the past month
4. No acupuncture or moxibustion treatment received in the previous 3 months
5. Willingness to be randomly assigned; understanding and signing the informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
190

Key exclusion criteria
1. Diagnosis with inflammatory arthritis, gout, acute knee joint injury or other knee arthritis (without cartilage involvement), meniscus injury, ligament injury and intra-articular fracture
2. Presence of serious heart diseases, kidney diseases, liver diseases or malignant tumors (unless the patient was surgically treated and with no relapse more than 5 years), systemic infection or contagious diseases
3. Intra-articular corticosteroid or hyaluronate injections (as well as any knee surgery or topical use of medication) during the past 6 months, or previous history of knee surgery
4 Previous experience with drug tests

Date of first enrolment
01/08/2010

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
China

Study participating centre
9408, 1200 Cailun Rd.
Shanghai
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201203

Sponsor information

Organisation
Shanghai University of Traditional Chinese Medicine (China)

Sponsor details
c/o Huangan Wu
650, South Wanping Rd.
Shanghai
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200030

Sponsor type
University/education

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 (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 and the Shanghai Municipal Science Foundation (11DZ1973300)

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	01/06/2020	17/12/2020	Yes	No