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Effects of laser moxibustion on patients with knee osteoarthritis

Submission date
14/03/2017

Recruitment status
No longer recruiting

Registration date
16/03/2017

Overall study status
Completed

Last Edited
08/04/2024

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 observe the effect and safety of CO2 laser irradiation on acupuncture points (laser moxibustion) in patients with knee osteoarthritis.

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

What does the study involve?
Participants are randomly allocated to be treated with either real (verum) or sham laser 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 at the start of the study, week 2 (mid-term), week 4 (the end of treatment), week 8, 12 and 24.

What are the possible benefits and risks of participating?
Laser 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. Shuguang Hospital affiliated to Shanghai University of Traditional Chinese Medicine (China)
2. Renji Hospital affiliated to Shanghai Jiaotong University (south part) (China)
3. Shanghai East Hospital affiliated to Tongji University (China)
4. Shanghai Tongren Hospital affiliated to Shanghai Jiaotong University (China)
5. Shanghai Hudong Hospital (China)

When is the study starting and how long is it expected to run for?
January 2014 to December 2018

Who is funding the study?
1. National Basic Research Program of China
2. National Natural Science Foundation of China
3. Shanghai development office of Traditional Chinese Medicine

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 (China)
1200 Cailun Road
Pudong new district
Shanghai
China
201203
+86 (0)21 51322175
sxy1@shutcm.edu.cn

Type(s)
Public

Contact name
Dr Ke Cheng

Contact details
1200 Cailun Road
Pudong district
Shanghai
China
201203
+86 (0)21 51322605
cheng_ker@hotmail.com

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Effectiveness of CO2 laser moxibustion treatment for knee osteoarthritis: a double-blind randomized controlled trial

Study objectives
A 4-week CO2 laser moxibustion treatment regimen reduces pain among patients with knee OA as compared with sham laser 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)
Current ethics approval as of 28/08/2018:
1. Institutional Review Board (IRB) of Shuguang hospital affiliated to Shanghai University of traditional Chinese medicine, No. 2014-341-37-01 (2014/08/13), No. 2014-341-37-02 (2015/08/13), No. 2014-341-37-03 (2016/08/31).
2. IRB of Shanghai East Hospital affiliated to Tongji University, 2014/10, No. 2013-24
3. IRB of Renji Hospital affiliated to Shanghai Jiaotong University, 2015/02/25, No. 2015-001
4. IRB of Shanghai Changning Tianshan Traditional Chinese Medicine Hospital, 2017/07/14, No. 2017TSKY04
5. IRB of Shanghai Tongren Hospital affiliated to Shanghai Jiaotong University, 2018/06/01, No. 2018-006-02

Previous ethics approval as of 24/08/2018:
1. Institutional Review Board (IRB) of Shuguang hospital affiliated to Shanghai University of traditional Chinese medicine, 13/08/2014, No. 2014-341-37-01
2. IRB of Shanghai East Hospital affiliated to Tongji University, 2014/10, No. 2013-24
3. IRB of Renji Hospital affiliated to Shanghai Jiaotong University, 2015/02/25, No. 2015-001
4. IRB of Shanghai Changning Tianshan Traditional Chinese Medicine Hospital, 2017/07/14, No. 2017TSKY04
5. IRB of Shanghai Tongren Hospital affiliated to Shanghai Jiaotong University, 2018/06/01, No. 2018-006-02

Previous ethics approval:
1. Institutional Review Board (IRB) of Shuguang hospital affiliated to Shanghai University of traditional Chinese medicine, 13/08/2014, ref: 2014-341-37-01
2. IRB of Shanghai East Hospital affiliated to Tongji University, October 2014, ref: 2013-24
3. IRB of Renji Hospital affiliated to Shanghai Jiaotong University, 25/02/2014, ref: 2015-001
4. IRB of Shanghai Tongren Hospital affiliated to Shanghai Jiaotong University, 14/03/2017, ref: 2017-32

Study design
Randomized multi-center double-blind placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Knee osteoarthritis

Interventions
Patients with knee osteoarthritis are randomly allocated into either verum or sham CO2 laser moxibustion groups. Patients receive verum or sham laser moxibustion treatment on Dubi (ST-35) and an Ashi (tender) point 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 are assessed at baseline, week 2 (mid-term), week 4 (the end of treatment), week 8, 12 and 24 after baseline.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome(s)
Knee pain, measured using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain scores from baseline to 4 weeks. The most painful joint reported by participants at baseline is assessed during the whole study. Change of WOMAC pain is also assessed at week 2, 8, 12, and 24.

Key secondary outcome(s))
1. Knee function, measured using the WOMAC function scores at week 4. It is also assessed at week 2, 8, 12, and 24
2. Knee stiffness, measured using the WOMAC stiffness score, and WOMAC overall score at baseline, week 2, 4, 8, 12 and 24
3. Pain, measured using the visual analog scale (VAS) at baseline, week 2, 4, 8, 12 and 24
4. Health-related quality of life, measured using the Short Form 36 (SF-36) component scales at baseline, week 4, 12 and 24
5. Walking ability, measured using the 50-feet (i.e., 15.24 meters) walking time at baseline, week 4 and 12
6. Patients' global assessment of OA, evaluated on a five point Likert scale at week 4
7. Guess of the group assignment to assess the masking effectiveness of the trial:
7.1. Guess from the treatment providers at week 4
7.2. Guess from the participants of their allocation at week 1 after the first treatment and at week 4
8. Assessment of safety: any adverse event, whether related to treatment or not, reported by the participants and practitioners at every visit. During the 20-week follow-up period (from week 5 to week 24), each participant is telephoned every week to follow any adverse event or side effect that occurs. Serious adverse effects are reported to DSMB and Medical Ethics Committee. The participants are asked to assess the safety of the treatment after 4 weeks' treatment, in terms of four grades: safe, relatively safe, unsafe, and very unsafe
9. Participants' sensations, asked during the treatment at every visit
10. Usage of medication, measured using a Medication Usage Log to record their daily intake of pain medications prescribed on a symptom-contingent (i.e., as per necessary, prn) basis

Exploratory outcome:
Serum levels of IL-1β, COX-2, COMP, TNF-α, IL-6, IL-17, IL-8, IL-4, IL-10 and IL-13 (considered as

important cytokines involved in the progress of OA), measured using blood tests at baseline and week 4

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Diagnosed with idiopathic knee OA according to the American Rheumatism Association (ARA) classification criteria as follows: knee pain with three of the following or knee joint osteophyte with one of the following conditions:
1.1. Age over 50 years
1.2. Morning stiffness within 30 minutes of waking
1.3. Crepitus
1.4. Bony tenderness
1.5. Bony enlargement
1.6. No palpable warmth
2. Kellgren-Lawrence grade ≥ 1 (Kellgren Lawrence Grading Scale: Grade 1: doubtful narrowing of joint space and possible osteophytic lipping; Grade 2: definite osteophytes, definite narrowing of joint space, Grade 3: moderate multiple osteophytes, definite narrowing of joints space, some sclerosis and possible deformity of bone contour; Grade 4: large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone contour)
3. Moderate or greater clinically significant knee pain on most days during the past month. A minimum score of 40 of 100 on a visual analogue scale VAS at baseline is an inclusion requirement
4. Willingness to be randomly assigned, understanding and signing the informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
50 years

Sex
All

Total final enrolment
392

Key exclusion criteria
1. Patients are screened by blood tests (rheumatoid factor (RF), erythrocyte sedimentation rate (ESR), etc) to rule out the possibilities of rheumatoid arthritis
2. Patients with fibromyalgia syndrome, and chronic fatigue syndrome, and ankylosing

spondylitis are excluded to rule out their impact on outcome assessment
3. Use of steroid medication in the past 3 months
4. Acupuncture or moxibustion treatment received in the previous 3 months
5. Intra-articular hyaluronate injection during the past 6 months
6. Arthrocentesis or arthroscopy in the past 1 year
7. Previous history of knee/hip replacement surgery, and plan to have such surgery during the trial
8. Use of other external treatment like topical use of medication
9. Presence of serious medical conditions, including heart diseases, pulmonary diseases, kidney diseases, liver diseases or malignant tumors, systemic infection or contagious diseases and psychopathy
10. Use of trial drug in the past 30 days
11. Previous participation in other sham-controlled laser therapy
12. Recruited in other clinical trial simultaneously
13. Unable to fill measurement questionnaires

Date of first enrolment
01/12/2014

Date of final enrolment
30/06/2018

Locations

Countries of recruitment
China

Study participating centre
Shuguang Hospital affiliated to Shanghai University of Traditional Chinese Medicine
185 Puan Road
Luwan district
Shanghai
China
200021

Study participating centre
Renji Hospital affiliated to Shanghai Jiaotong University (Pudong Branch)
2000 Jiangyue Road
Pudong new district
Shanghai
China
201112

Study participating centre

Shanghai East Hospital affiliated to Tongji University
150 Gimo Road
Pudong new district
Shanghai
China
200120

Study participating centre
Shanghai Tongren Hospital affiliated to Shanghai Jiaotong University
Shanghai
China
200336

Study participating centre
Shanghai Hudong Hospital
95 Boxing Rd
Pudong new district
Shanghai
China
200129

Sponsor information

Organisation
Shanghai University of Traditional Chinese Medicine (China)

ROR
https://ror.org/00z27jk27

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China (81320108028)

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
National Basic Research Program of China (2015CB554505)

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

Results and Publications

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 Ke Cheng (cheng_ker@hotmail.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2020	28/01/2020	Yes	No
Results article		22/11/2023	08/04/2024	Yes	No
Protocol article	protocol	01/08/2020	26/11/2020	Yes	No