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Acupuncture and moxibustion treatment for Crohn's disease

Submission date
11/02/2017

Recruitment status
No longer recruiting

Registration date
21/02/2017

Overall study status
Completed

Last Edited
20/02/2017

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Crohn’s disease (CD) is a long-term condition which causes inflammation (swelling) in the digestive system (gut). Although it can affect any part of the gut, it is most common at the end of the ileum (the last part of the small intestine) or the colon (the large intestine). It can alternate between remission (when the disease is not active) and flare-ups (when the disease is active and causing symptoms). Currently, there is no cure for CD. However, there are alternative medicines and treatments that aim to control the disease. Acupuncture is a traditional Chinese therapy that inserts small needles in certain areas of the body in order to help control pain. Sometimes acupuncture is done in combination with moxibustion which is a traditional Chinese medicine therapy consisting of burning a Chinese herb called Mugwort. Some studies have suggested that acupuncture and moxibustion can effectively help control CD. This study aims to see if acupuncture and moxibustion impact Crohn’s disease and if there is any genetic change (change in DNA) in response to the treatment.

Who can participate?
Adults aged 16 to 70 who are diagnosed with Crohn’s disease.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive acupuncture and moxibustion treatment at particular points on the body. This involves inserting thin needles into the skin and burning a certain type of stick over the skin for 30 minutes. Those in the control group receive placebo (fake) acupuncture and moxibustion treatment at the same points on the body as the first group. The treatments in both groups are performed once every other day for 30 minutes, three times a week, for a total of 24 weeks of treatment. At the end of the study participants are followed up to compare the outcomes of each group and to see how the treatments impact Crohn’s disease.

What are the possible benefits and risks of participating?
Participants may benefit from receiving free treatments, clinical examinations and a small monetary compensation. There are no notable risks but participants may feel discomfort or pain at the sites the needles are inserted. Some patients may experience skin flushing or blistering one day after treatment.

Where is the study run from?
Shanghai Research Institute of Acupuncture and Meridian (China)

When is the study starting and how long is it expected to run for?
February 2017 to December 2020

Who is funding the study?
National Natural Science Foundation of China (China)

Who is the main contact?
Dr Bao Chunhui
baochunhui789@126.com

Contact information

Type(s)
Public

Contact name
Dr Bao Chunhui

Contact details
650 South Wanping Road
Xuhui District
Shanghai
China
200030
+86 21 64395973
baochunhui789@126.com

Type(s)
Public

Contact name
Prof Shi Yin

Contact details
650 South Wanping Road
Xuhui District
Shanghai
China
200030
+86 21 64383910
flysy0636@hotmail.com

Additional identifiers

Protocol serial number
Version 2.0

Study information

Scientific Title
Study on the regulatory mechanism of acupuncture and moxibustion on autophagy mediated by chromatin remodeling in Crohn's disease

Study objectives
The aim of this study is to observe the efficacy and safety of acupuncture and moxibustion for Crohn's disease and chromatin remodeling mediated CD autophagy mechanism of epigenetic regulation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
IRB of Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of TCM, 22/12/2016, ref: 2016-101

Study design
Single-blind single-center randomised controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Crohn's Disease

Interventions
Participants are randomly allocated to one of two groups. Randomisation is conducted using a computer-generated numbers placed sequentially in envelopes and kept by a clinician with no contact to the participants.

Group 1: Experimental acupuncture-moxibustion
Participants in this group receive acupuncture treatment at bilateral acupoints ST37, SP6, SP9, SP4, LR3 and LI3. Sterile disposable stainless steel needles (with a diameter of 0.30 mm and length of 40 mm or 25 mm) with plastic casings and pedestals are used. The needles are directly inserted 20-30 mm into the skin to elicit a de-qi sensations. The needle is kept in position for 30 minutes. Participants also receive moxibustion treatment at the bilateral acupoints ST25 and ST36 . Mild-warm moxibustion is a type of moxa stick moxibustion that is performed by holding an ignited moxa stick a certain distance above the patient's skin, keeping the spot warm and making it reddened, but not burnt. This is done using mild-warm moxibustion that keeps transcutaneous temperature at 43 °C ± 1 °C, for 30 minutes at each acupoint. Moxibustion and acupuncture are performed at the same time once every other day, three times a week, for a total of 24 weeks of treatment.

Group 2: Placebo acupuncture-moxibustion group
Participants in this group receive sham acupuncture at the same acupoints spots as the

experimental group. The same type of needles are used as in the experimental group. The needles in this group are onlytouched to the skin and not inserted into the skin therefore it does not elicit a de-qi sensation. Participants receive a sham moxibustion treatment at the same time as the acupuncture treatment. This is performed by using an ignited moxa stick at a further distance from the participants skin than in the experimental group, which keeps the transcutaneous temperature at 37 °C ± 1 °C. Moxibustion and acupuncture are performed once every other day, three times a week, for a total of 24 weeks of treatment.

Participants are followed up at 12 weeks, 24 weeks and 48 weeks to examine the impact of this treatment on managing Crohn's disease and to see if it changed the pathogenic findings.

Intervention Type
Mixed

Primary outcome(s)
Disease severity is measured using the Crohn's disease activity index (CDAI) at baseline, 6, 12 and 24 weeks.

Key secondary outcome(s))
1. Quality of life is measured using the Inflammatory Bowel Disease Questionnaire (IBDQ) at baseline, 12 and 24 weeks
2. Psychological factors are measured using the Hospital anxiety and depression scale (HADS) at baseline, 12 and 24 weeks
3. Disease activity are measured using blood (C-reaction protein, Erythrocyte sedimentation rate, blood platelet) at baseline,12 and 24 weeks
4. Endoscopic findings are measured using the Simple Endoscopic Score for Crohn's Disease (SES-CD) at baseline and 48 weeks
5. Pathogenic manifestations are measured using the Histological techniques (Hematoxylin-eosin staining and Histological scores) at baseline and 48 weeks
6. Immunity-related issues are measured using the protein and messenger ribonucleic acid (mRNA) expression of autophagy related protein 16 like protein 1(ATG16L1), immunity-related GTPase family M protein (IRGM), and interleukin-18 at baseline, 12 and 24 weeks

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Diagnosis of Crohn's disease
2. Aged 16-70
3. Patients with mild or moderate CD (CDAI between 151 and 450)
4. Not taking any medication or taking mesalazine, prednisone, immunosuppressive drugs
5. Did not take or no longer taking biological agents such as infliximab
6. Signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Pregnant or lactating patients
2. Associations with heart, brain, liver, kidney and hematopoietic system of serious diseases
3. Mental illness or other serious diseases
4. Presence of skin disease, fistula, sinus, mutilation and other conditions in the acupoints selected in the study that can not be implemented moxibustion treatment
5. Taking other medications that can lead to a CD symptom aggravating or changing the efficacy of drugs
6. Associations with short bowel syndrome, symptoms of intestinal stenosis,
7. Previous stomach or gastrointestinal tract surgery

Date of first enrolment
20/02/2017

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
China

Study participating centre
Shanghai Research Institute of Acupuncture and Meridian
650 South Wanping Road
Xuhui District
Shanghai
China
200030

Sponsor information

Organisation
Shanghai Research Institute of Acupuncture and Meridian

ROR
https://ror.org/02fc7xd23

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date