Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation the effectiveness of acupuncture on Inflammatory Bowel Disease patients

Protocol summary

Study aim
Investigating the efficacy of acupuncture in mild to moderate Crohn's disease (CD) and ulcerative colitis (UC) patients

Design
A randomized controlled trial with parallel groups on 56 patients. Sealedenvelope.com is used for stratified randomization

Settings and conduct
Patients who meet the inclusion criteria first sign the informed consent form and then are randomly divided into one of two intervention or control groups. In both groups, the needles are inserted into the skin, with the difference that in the intervention group, needling was done in acupoints with deqi depth, but in the control group, the needles were inserted superficially in non-acupoints, therefore the patients of both groups feel the needle entering the body. By referring to the acupuncture clinic of Imam Reza (AS) Mashhad University Hospital, patients receive a total of 16 acupuncture sessions during 8 weeks and 2 sessions per week. Scoring of disease severity and tests and quality of life questionnaire are measured at the beginning of the study, after the completion of the sessions and 8 weeks after that.

Participants/Inclusion and exclusion criteria
Patients diagnosed with CD or UC who have been diagnosed for at least 6 months and are in the mild to moderate category according to the criteria of Crohn's disease activity index between 150 and 450 or simple clinical colitis activity index between 3 and 11 and whose medications have been taken for two months The past has been unchanged. and do not have a history of acupuncture

Intervention groups
In the intervention group, real acupuncture is performed in the patients, and in the control group, sham acupuncture is performed in the form of superficial needle insertion in non-acupuncture points.

Main outcome variables
Crohn's Disease Activity Index (for CD patients); Simple Clinical Colitis Activity Index (for UC patients)

General information

Reason for update
Changing the date of patient admission

Acronym

IRCT registration information
IRCT registration number: **IRCT20231009059671N1**
Registration date: **2024-03-18, 1402/12/28**
Registration timing: **prospective**

Last update: **2025-09-11, 1404/06/20**
Update count: **4**

Registration date
2024-03-18, 1402/12/28

Registrant information

Name
Behnam Bahadori

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-22, 1404/04/01

Expected recruitment end date
2026-06-22, 1405/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the effectiveness of acupuncture on Inflammatory Bowel Disease patients

Public title
effect of acupuncture in inflammatory bowel disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients diagnosed with Crohn's disease or ulcerative colitis who have been diagnosed for at least 6 months and are classified as mild to moderate according to the criteria of Crohn's disease activity index between 150 and 450 or simple clinical colitis activity index between 3 and 11 Consistency of drugs used in the last two months Sign informed consent
Exclusion criteria:
disease or skin lesion at the location of acupuncture points using adalimumab history of abdominal surgery in the last 6 months serious systemic disease using anticoagulant or thrombolytic drugs history of skin allergy and needle or metal allergy known psychiatric illness severe extraintestinal complications related to inflammatory bowel disease such as severe skin problems or thromboembolic problems fistula, abscess, intestinal obstruction, intestinal perforation history of acupuncture pregnancy
Age
From **16 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method will be stratified, Crohn's and ulcerative colitis patients will be randomly and equally divided into intervention and control groups. A random sequence is generated using sealedenvelope.com based on permuted random blocks, and random numbers are printed and placed inside opaque sealed envelopes. The lid of the envelopes will be closed and its contents will not be visible from the outside. Then, first, the purpose of the study is explained to the person who meets the inclusion criteria, and if the person wishes, he signs the informed consent form and takes an envelope and then opens it, and based on the contents of the envelope, the person enters one of the two groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients who are treated with acupuncture or sham acupuncture (sham) are blinded in such a way that needles are inserted into both groups under the same conditions, in the acupuncture group at the acupuncture points and at the depth of deqi, but in the sham group at Non-acupuncture points and superficially with a maximum depth of 0.2 cm Also, the evaluator and the analyst will be unaware of the grouping done
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Vice-Chancellor of Research and Technology, Qureshi Building, next to Hoizeh Cinema, Daneshgah Street, Mashhad, Khorasan Razavi
City
Mashhad
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9138813944
Approval date
2024-02-24, 1402/12/05
Ethics committee reference number
IR.MUMS.REC.1402.329

Health conditions studied

1

Description of health condition studied
crohn's disease
ICD-10 code
K50
ICD-10 code description
Crohn's disease [regional enteritis]

2

Description of health condition studied
ulcerative colitis
ICD-10 code
K51
ICD-10 code description

Ulcerative colitis

Primary outcomes

1

Description
crohn's disease activity index
Timepoint
At the beginning of the study (before the start of the intervention), 8 weeks later (ending the intervention), 16 weeks later (follow-up)
Method of measurement
CDAI Scoring

2

Description
Simple clinical colitis activity index
Timepoint
At the beginning of the study (before the start of the intervention), 8 weeks later (ending the intervention), 16 weeks later (follow-up)
Method of measurement
SCCAI Scoring

Secondary outcomes

1

Description
inflammatory bowel disease questionnaire
Timepoint
At the beginning of the study (before the start of the intervention), 8 weeks later (ending the intervention), 16 weeks later (follow-up)
Method of measurement
inflammatory bowel disease questionnaire-32

2

Description
stool calprotectin test
Timepoint
At the beginning of the study (before the start of the intervention), 8 weeks later (ending the intervention), 16 weeks later (follow-up)
Method of measurement
stool sampling

3

Description
CRP test
Timepoint
At the beginning of the study (before the start of the intervention), 8 weeks later (ending the intervention), 16 weeks later (follow-up)
Method of measurement
Blood sampling

4

Description
ESR test
Timepoint
At the beginning of the study (before the start of the intervention), 8 weeks later (ending the intervention), 16 weeks later (follow-up)
Method of measurement
Blood sampling

5

Description
Stool Exam
Timepoint
At the beginning of the study (before the start of the intervention), 8 weeks later (ending the intervention), 16 weeks later (follow-up)
Method of measurement
stool sampling

6

Description
Complete Blood Count
Timepoint
At the beginning of the study (before the start of the intervention), 8 weeks later (ending the intervention), 16 weeks later (follow-up)
Method of measurement
Blood sampling

Intervention groups

1

Description
Intervention group: Patients in the intervention group receive acupuncture treatment twice a week for eight weeks and a total of 16 sessions. Each acupuncture session lasts about 30 minutes. The points include KID3(taixi), LIV3(taichong), ST25(tianshu), ST40(fenglong), ST36(zusanli), LI4(hegu), LI11(quchi), SP4(gongsun), SP6(sanyinjiao), SP9(yinlingchuan).) , SP15(daheng) , BL18(ganshu) , BL20(pishu) , BL23(shenshu) , BL25(dachangshu) , PC6(neiguan) , HT7(shenmen) , CV4(guanyuan) , CV6(qihai) , CV9(shuifen)), CV12(zhongwan), GV20(baihui), GV4(mingmen) with needles of size 0.25*40 and is inserted to the depth of deqi
Category
Treatment - Other

2

Description
Control group: Patients in the control group, like the intervention group, receive 16 sham acupuncture sessions twice a week for eight weeks. Each session lasts about 30 minutes. The points with a distance from the acupuncture points in non-acupuncture point and non-meridian places are injected shallowly with the same

number and size of needles as the intervention group.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Acupuncture Clinic of Imam Reza Hospital (AS)

Full name of responsible person
Seyed Kazem Farahmand

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Acupuncture Clinic of Imam Reza Hospital (AS), Daneshgah Street, Shariati Square

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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Behnam Bahadori

Position
Student

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Information about the disease of the participants and the results of the study in each of the groups
When the data will become available and for how long
The access period starts from the time the results are printed
To whom data/document is available
All researchers
Under which criteria data/document could be used
To carry out research and treatment
From where data/document is obtainable
Dr. Behnam Bahadori Acupuncture Clinic of Imam Reza Hospital, Mashhad 00989039825573
What processes are involved for a request to access data/document
Review by the research team, review by the department and faculty, classification and data submission
Comments