Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Comparison of the effect of saffron enema with placebo in controlling the disease of patients with ulcerative colitis based on Mayo score

Protocol summary

Study aim

the affect of saffron solution enema on Ulcerative colitis activity

Design

The clinical trial has a control group with blind and two-way groups that randomly assign patients to the two groups will be done using graph pad software. The sample size was calculated using gpower software and considering the high effect rate (0.4) and considering the power of 80% and alpha error of 0.05, 52 people (26 people in each group were calculated. 60 people (30 patients in each group) will be studied.

Settings and conduct

The practical location of the project is Tabriz Medical School. Patients in the control group are prescribed Iranian mesalazine tablets 2 grams daily and saffron dye solution enema as a placebo in the amount of 50 cc daily for 4 weeks. The intervention group is prescribed 2 grams of mesalazine tablets and a solution of saffron solution as a solution of 300 mg of saffron in 50 cc of water daily for 4 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients with newly diagnosed disease or with recent recurrence who can accept and tolerate enema. Exclusion criteria: 1. Patients with controlled disease 2. Patients who do not tolerate enema. 3. Patients with comorbidities 4. Pregnant or lactating patients

Intervention groups

In this randomized, double-blind study, 60 patients with ulcerative colitis were selected by available sampling and entered the study. These patients are randomly divided into two groups. Patients in the control group are prescribed Iranian mesalazine 2 g daily and saffron dye solution as a placebo in the amount of 50 cc daily for 4 weeks. The intervention group is prescribed 2 grams of mesalazine and a solution of saffron solution as a solution of 300 mg of saffron in 50 cc of water daily for 4 weeks.

Main outcome variables

The primary outcome in this study is the severity of the disease, which will be measured using the mayo score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190701044062N5**
Registration date: **2021-04-03, 1400/01/14**
Registration timing: **retrospective**

Last update: **2021-04-03, 1400/01/14**
Update count: **0**

Registration date

2021-04-03, 1400/01/14

Registrant information

Name

manouchehr khoshbaten

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 1334 3010

Email address

mkhoshbaten@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of saffron enema with placebo in controlling the disease of patients with ulcerative colitis based on Mayo score

Public title

Effect of saffron solution on ulcerative colitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who's disease is diagnosed recently or recent relapce Patients who can tolerate enema

Exclusion criteria:

Patients with good controlled disease Patients who can't tolerate enema Patients with associated disease: Crohn, Intermediate colitis, CMV, Pseudomembrano colitis, Heart failure, Renal failure, PSC

Age

No age limit

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of patients to two groups will be done using graph pad software. Random numbers will only be available to the head nurse until the end of the study. Patients and specialists evaluating the severity of the disease and the statistical analyst will be blind to the allocation of individuals to study groups until the end of the study. And the desired solutions are marked with A and B and will be provided by the nurse.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and specialists evaluating the severity of the disease and the statistical analyst will be blind to the allocation of individuals to study groups until the end of the study

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

The central building of Tabriz University of Medical Science,Golgasht St.,Azadi St.

City

Tabriz

Province

East Azarbaijan

Postal code

5154751637

Approval date

2020-08-01, 1399/05/11

Ethics committee reference number

IR.TBZMED.REC.1399.480

Health conditions studied

1

Description of health condition studied

Ulcerative Colitis

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes

1

Description

Disease activity based on Mayo score

Timepoint

Assessment of disease activity at the beginning of the study and 28 days after the start of saffron enema solution

Method of measurement

Mayo Score

Secondary outcomes

1

Description

Frequent defecation

Timepoint

Evaluation of stool frequency at the beginning of the study and 28 days after starting saffron enema solution

Method of measurement

Mayo Score

2

Description
Rectal bleeding
Timepoint
Evaluation of rectal bleeding at the beginning of the study and 28 days after starting saffron enema solution
Method of measurement
Mayo score

3

Description
Endoscopic findings
Timepoint
Evaluation of endoscopic findings at the beginning of the study and 28 days after starting saffron enema
Method of measurement
Mayo score

Intervention groups

1

Description
Intervention group: The intervention group is prescribed 2 grams of mesalazine tablets and saffron solution as a solution of 300 mg of saffron in 50 cc of water, daily for 4 weeks and the severity of the disease Will be evaluated by usin.g mayo score before and after the study
Category
Treatment - Drugs

2

Description
Control group: The control group is prescribed 2 grams of mesalazine tablets and saffron color's solution as a solution of 300 mg of saffron color in 50cc of water, daily for 4 weeks and the severity of the disease will be elevated by using mayo score before and after the study.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Manouchehr Khoshbaten
Street address
Imam Reza Hospital Clinic, Golgasht St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Ata Mahmoodpour
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Manouchehr Khoshbaten
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available