Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Nov 2026

Evaluation of the effect of Thymus kotschyanus Boiss. & Hohen. in improving ulcerative colitis symptoms

Protocol summary

Study aim
Conduct a double blind randomized placebo control trial in UC patients to evaluate efficacy and anti-inflammatory effect of Thymus kotschyanus extraction as an additive treatment.

Design
A randomized, double-blinded, placebo controlled clinical trial with a parallel group design of 30 patients. Randomization will be performed with computer software.

Settings and conduct
30 out-patients with colitis will be selected and randomly assigned to two groups of 15 individuals (Imam Reza hospital, Mashhad, Razavi Khorasan). Then the clinical symptoms and laboratory results of the patients will be monitored on days 0 and 90 from the beginning of the intervention

Participants/Inclusion and exclusion criteria
Inclusion criteria were: (1)ulcerative colitis out-patients (2) age between 13 and 65 yrs (3)the Simple Clinical Colitis Activity Index (SCCAI) between 5 and 13 (4) taking mesalazine with fixed dose since 1 month ago and not exceed more than 4.5 grams mesalazine in a day(5) if taking topical mesalazine it should be used at least for 2 weeks with a fixed dose and not exceed more than 4 grams in a day(6) hemoglobin higher than 10 Exclusion criteria were: (1) incidence of any adverse reaction of T.kotschyanus extraction (2) diagnosing concurrent disease such as diabetes, cardiovascular disease, kidney disease, liver diseases,thyroid disease, and bile disease (3) having leukopenia, thrombocytopenia or other blood coagulation disorders (4) concurrent sepsis or any active infection (5) administering another anti-inflammatory or immunomodulatory or anti-coagulant medicine (6) having epilepsy and convulsion (7) pregnancy and lactation (8) being reluctant to continue this trial.

Intervention groups
The control group receives standard colitis with placebo. The intervention group receives standard colitis drugs with extract capsule.

Main outcome variables
reduction in SCCAI score and calprotectin protein

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200406046965N2**
Registration date: **2021-09-20, 1400/06/29**
Registration timing: **prospective**

Last update: **2021-09-20, 1400/06/29**
Update count: **0**

Registration date
2021-09-20, 1400/06/29

Registrant information

Name
Seyed Ahmad Emami

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3180 1267

Email address
emamia@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2021-11-22, 1400/09/01

Actual recruitment start date
2021-09-23, 1400/07/01

Actual recruitment end date

2021-12-06, 1400/09/15

Trial completion date

2022-03-06, 1400/12/15

Scientific title

Evaluation of the effect of Thymus kotschyanus Boiss. & Hohen. in improving ulcerative colitis symptoms

Public title

Evaluation of the effect of Thymus kotschyanus Boiss. & Hohen. in improving ulcerative colitis symptoms

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who were diagnosed by ulcerative colitis and not been hospitalized during this clinical trial Patients must be between 13 and 65 years' old The Simple Clinical Colitis Activity Index (SCCAI) score must be higher than 5 and less than 13 Patients must have taken mesalazine with fixed dose since at least 1 month ago and not exceed more than 4.5 grams mesalazine in a day If patients have administered topical mesalazine it should be used at least for 2 weeks with a fixed dose and not exceed more than 4 grams in a day Patients shouldn’t have taken another anti-inflammatory or immunomodulatory medicine except mesalazine Hemoglobin must be higher than 10 No concurrent disease such as diabetes, cardiovascular disease, kidney disease, liver disease, thyroid disease, bile disease No concurrent leukopenia, thrombocytopenia or other blood coagulation disorders No concurrent sepsis or any active infection No pregnancy or breast feeding No taking any anti-coagulant medicine No history for epilepsy or convulsions

Exclusion criteria:

Acute severe ulcerative colitis requiring hospital admission (SCCAI >13); inactive disease (SCCAI < 3). A history of sensitivity to Thymus kotschyanus or its preparations. A history of diabetes, cardiovascular diseases, kidney disease, liver diseases, thyroid disease, bile disease and leukopenia, thrombocytopenia. Hemoglobin less than 10. Pregnancy. Reluctance to continue this trial.

Age

From **13 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Random sequence generation: a computer software was performed and randomization sequence was used to receive active herbal remedy or placebo. This sequence contained two letters : A for Thymus kotschyanus and B for placebo. Allocation concealment: a person except the executer, stick the letter A and B on the capsule boxes based on computer software randomization. Execution of random allocation process: B:A person who evaluates and registers researchers in terms of inclusion and exclusion criteria. A:The person who has assigned the participants to the groups: Gastroenterologists, does not interfere in other stages of randomization, including registration and allocation of participants.

Blinding (investigator's opinion)

Double blinded

Blinding description

The treatment drug and placebo are given as same-colored and same-sized capsule with containers in boxes labeled with the letters A and B. The medical staff, the patient and the data collector are unaware of the nature of the drug or placebo and of the content of the boxes. The executor of this research project is the only person aware of the contents of boxes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Ethics Committee of Mashhad University of Medical SciencesMedical Ethics Committee of Mashha

Street address

School of Pharmacy, University Campus, Vakil Abad boulvard

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948954

Approval date

2020-04-13, 1399/01/25

Ethics committee reference number

IR.MUMS.REC.1399.092

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
Reduction in SCCAI score
Timepoint
12 weeks after intervention beginning.
Method of measurement
Filling the questionnaire for SCCAI score .

2

Description
Reduction in calprotectin protein
Timepoint
12 weeks after intervention beginning.
Method of measurement
Measuring the laboratory test for fecal calprotectin.

Secondary outcomes

1

Description
Remission and improvement changes in SIBDQ scores
Timepoint
12 weeks after intervention beginning.
Method of measurement
Filling the SIBDQ questionnaire.

2

Description
Reduction in SEO index
Timepoint
12 weeks after intervention beginning.
Method of measurement
Measuring the related laboratory test for SEO index.

3

Description
Finding T. kotschyanus possible adverse effects.
Timepoint
Week 4 and 8 and 12 after intervention beginning.
Method of measurement
Asking patients about any adverse reaction incidence.

Intervention groups

1

Description
Intervention group: consisted of 15 patients who were randomized by computer took one extraction capsule three times a day by the effective daily dose 0.5 grams of T. kotschyanus beside the standard colitis treatment regimen. These patients administered the extraction capsule for 3 months by the total dose of 45 grams of the extraction in the whole time of trial. The capsules will be prepared at the School of Pharmacy, Mashhad University of Medical Sciences.
Category
Treatment - Drugs

2

Description
Control group: 15 patients who were randomized by computer took one placebo capsule three times a day for 3 months beside the standard colitis treatment regimen. The placebo capsules ill be prepared at the School of Pharmacy, Mashhad University of Medical Sciences.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Hooman Mosanan Mozaffari
Street address
Imam Reza Square, Ebne-sina Street
City
Mashhad
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Razavi Khorasan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Seyed Ahmad Emami
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Email
emamia@mums.ac.ir
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
Seyed Ahmad Emami
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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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
Not applicable