Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Investigating the effect of Plantago major on clinical symptoms of Ulcerative colitis

Protocol summary

Study aim

Investigating the effect of Plantago major on clinical symptoms of Ulcerative colitis

Design

Double blind clinical trial.The eligible persons of patients with symptoms of Ulcerative colitis, that confirmed by colonoscopy and biopsy, will be chosen and then will be randomly categorized into intervention or control group.Finally,the effect of Plantago major on severity of disease symptoms will be evaluated.Intervention group:Prescribed chemical drugs with Plantago major and Control group: Prescribed chemical drugs with placebo.Sample size:50 Phase:3

Settings and conduct

Site:Gastroentrology clinic, Imam Khomeiny hospital, Urmia.General Mizaj in 0, 8 w., Severity of symptoms in 0, 4, 8 w. according to Lichtiger Clinical Index,and Drug side effects in 4, 8 w.,will be evaluated.Research fellow and participants are blinded to drug type.

Participants/Inclusion and exclusion criteria

Include:1.Having the clinical symptoms of Ulcerative colitis that confirmed by endoscopy and biopsy2.Age 15-70 years Exclude:1.Pregnancy or breast feeding2.Massive bleeding or need to hospitalization or emergent surgery3.Fulminant colitis, Peritonitis, Toxic megacolon, Colorectal cancer, Stricture, Obstruction4.Using of Antibiotics, Herbal drugs,OCPs, NSAIDs or Hormonal therapy(in last 2 weeks(w.))5.Concurrent important and severe disease:liver, kidney or heart disease, cancer or Celiac disease6.Cigarette or opioids addiction

Intervention groups

Intervention group: Capsule 600mg of Plantago major roasted seed, 2 cap. 30 minutes before meals(totally 6 cap. in day), up to 8 w. and Control group: Capsule 600mg of roasted Wheat flour, 2 cap. 30 minuts before meals(totally 6 cap. in day), up to 8 w..All of the patients have their prescript chemical drugs.

Main outcome variables

Severity of clinical symptoms of Ulcerative colitis (remission, mild, moderate, sever)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181018041375N1**
Registration date: **2018-12-17, 1397/09/26**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-17, 1397/09/26**
Update count: **0**

Registration date

2018-12-17, 1397/09/26

Registrant information

Name

Atiyeh Baghizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5121 4055

Email address

a.baghizadeh@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-10, 1397/09/19

Expected recruitment end date

2019-06-09, 1398/03/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effect of Plantago major on clinical symptoms of Ulcerative colitis

Public title
Effect of Plantago major on Ulcerative colitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having the clinical symptoms of Ulcerative colitis that confirmed by endoscopy and biopsy Age 15-70 years

Exclusion criteria:
Pregnancy or breast feeding Massive bleeding or need to hospitalization or emergent surgery Fulminant colitis, Peritonitis, Toxic megacolon, Colorectal cancer, Stricture, Obstruction Using of Antibiotics, Herbal drugs,OCPs, NSAIDs or Hormonal therapy(in last 2 weeks) Concurrent important and severe disease:liver, kidney or heart disease, cancer or Celiac disease Cigarette or opioids addiction

Age
From **15 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The expert of center,accomplish the permuted block randomization(quadruple blocks) and codification of boxes(1 to 50), and the research fellow hands over the boxes to patients sequentially, while she is unaware of their content.Due to blinding, the last allocation in each block stays confidential.

Blinding (investigator's opinion)
Double blinded

Blinding description
The research fellow and participant are blinded to boxes contents(drug or placebo),and the boxes are handed over sequentially due to their codes(double blind trial)

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee on Research of Shahed University

Street address
Shahed University, Opposite to Imam Khomeini holy shrine, Persian Gulf highway (Tehran-Qom), Tehran

City
Tehran

Province
Tehran

Postal code
3319118651

Approval date
2018-09-03, 1397/06/12

Ethics committee reference number
IR.SHAHED.REC.1397.037

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
Severity of clinical symptoms of Ulcerative colitis (remission, mild, moderate, sever)

Timepoint
0, 4, 8 weeks

Method of measurement
Lichtiger Clinical Index

Secondary outcomes

1

Description
Drug side effects

Timepoint
4, 8 weeks

Method of measurement
Drug side effects questionnaire

2

Description

General Mizaj

Timepoint

0, 8 weeks

Method of measurement

Mojahedi Mizaj questionnaire

Intervention groups

1

Description

Intervention group: Prescribed chemical drugs with capsule 600mg of Plantago major roasted seed, 2 cap. 30 minuts before meals(totally 6 cap. in day), up to 8 weeks

Category

Treatment - Drugs

2

Description

Control group: Prescribed chemical drugs with capsule 600mg of roasted Wheat flour, 2 cap. 30 minuts before meals(totally 6 cap. in day), up to 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroentrology clinic, Imam Khomeiny hospital

Full name of responsible person

Atiyyeh Baaghizadeh

Street address

Imam Khomeini hospital, Ershad Ave., Modarres Blvd.

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Province

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Dr. Zahra Kiasalari

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Web page address

http://shahed.ac.ir/research/Pages/Home.aspx

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahed University

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

Shahed University

Full name of responsible person

Aiyyeh Baaghizadeh

Position

PhD Candidate of Iranian Traditional Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Associate professor

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Public Health/Community Medicine

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Medical doctor

Other areas of specialty/work
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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