Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Evaluation the efficacy of Achillea wilhelmsii capsule in ulcerative colitis patients:a randomized double blind placebo controlled clinical trial

Protocol summary

Summary

The goal of this study is to prescribe Achillea wilhelmsii capsule for patients with ulcerative colitis and evaluation the efficacy of it in a randomized double blind placebo controlled clinical trial. This study is done in Emam khomeini hospital and Emam reza hospital of Kermanshah university of medical science . 44 patients are treated randomly with capsules containing 250 mg Achillea wilhelmsii powder or placebo orally twice a day for 30 days. Response to the medication in patients under the treatment will be evaluated based on Mayo score (Disease Activity Index) and a blood test for hematologic and biochemical evaluation will be done at the beginning and the end of study. Inclusion criteria: age>18- ability to swallow the capsule- patients who are not cured with Achillea wilhelmsii during a last month.- Patients who their diseases are approved by complete medical evaluation, colonoscopy, pathology and laboratory data.-Only patients with mild to moderate ulcerative colitis. Exclusion criteria: smokers- pregnant patients and nursing mothers- Patients who have to use other drugs that interference with this medication.- patients who are disposed to a serious health danger, such as severe cardiac, liver or renal diseases.- In case of appearing significant side effects- patients with severe allergy to this plant (dermatitis contact).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102620071N2**
Registration date: **2017-01-22, 1395/11/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-01-22, 1395/11/03

Registrant information

Name

Mohammad Hosein Farzaei

Name of organization / entity

Faculty of Pharmacy, Kermanshah University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2016-11-25, 1395/09/05

Expected recruitment end date

2017-02-23, 1395/12/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the efficacy of Achillea wilhelmsii capsule in ulcerative colitis patients:a randomized double blind placebo controlled clinical trial

Public title

Evaluation the efficacy of Achillea wilhelmsii capsule in ulcerative colitis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:age>18- ability to swallow the capsule- patients who sign the testimonials and cooperate during the study.(In cases which patients do not have education,the investigator should read the testimonial for them.if they are satisfied, the investigator can include them to the study.)- patients who are not cured with Achillea wilhelmsii during a last month.-Patients who their diseases are approved by complete medical evaluation, colonoscopy, pathology and laboratory data.- Only patients with mild to moderate ulcerative colitis can be include to this study. Exclusion criteria:smokers- pregnant patients and nursing mothers-patients who have to use other drugs that interference with this medication (such as systemic NSAID, antihistamins or systemic antibiotics during last 2 weeks)- patients who are suffering from other diseases in addition to ulcerative colitis that the etiology of them are oxidative stress, such as metabolic syndrome, diabetic leg ulcer, coronary arterial disease, pulmonary infection, patients who are disposed to a serious health danger, such as severe cardiac, liver or renal diseases.- If significant side effects occur, the patient will be excluded from the study and followed to end of the study.- If a patient do not want to continue to cooperating for any reasons, he will be excluded from the study.- patients with severe allergy to this plant (dermatitis contact) will be excluded.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization is performed using blocking method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Kermanshah university of medical sciences

City

Kermanshah

Postal code

Approval date

2016-10-19, 1395/07/28

Ethics committee reference number

KUMS.REC.1395.448

Health conditions studied

1

Description of health condition studied

ulcerative colitis

ICD-10 code

k51.9

ICD-10 code description

Ulcerative colitis, unspecified

Primary outcomes

1

Description

number of excretion daily

Timepoint

before using the drug-2 weeks after using the drug-30 days after using the drugs

Method of measurement

based on Mayo clinic questionary and ESR,CBC,CRP

2

Description

Rate of rectal bleeding

Timepoint

before using the drug-2 weeks after using the drug-30 days after using the drugs

Method of measurement

based on Mayo clinic score, CRP, CBC, and ESR

Secondary outcomes

1

Description

photo sensitivity- gastrointestinal disorders

Timepoint

Two weeks after using the drug- 30 days after using the drug

Method of measurement

based on side effect questionary

Intervention groups

1

Description

Two capsules (each capsule contains 250 mg Achillea

wilhelmsii) daily for a month, from Kermnanshah apothecary

Category

Treatment - Drugs

2

Description

Two capsules (each capsule contains 250 mg hydroxypropyl methylcellulose from Sigma company) daily for a month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam khomeini Hospital, Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hosein Farzaei

Street address

Emam khomeini Hospital, Kermanshah University of Medical Sciences

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Behrooz Hamzeh

Street address

Vice Chancellor for Research, Kermanshah university of medical sciences,

City

kermanshah

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for Research, Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of pharmacy, Kermanshah University of Medical Sciences

Full name of responsible person

Mahtab Amiri

Position

PharmacyStudent

Other areas of specialty/work

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Person responsible for scientific inquiries

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty