Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the efficacy of Achillea wilhelmsii capsule in irritable bowel syndrome 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 irritable bowel syndrome and evaluating ts efficacy. This study is a randomized double blind placebo controlled clinical trial which is done in Emam khomeini hospital and Emam reza hospital of Kermanshah University of Medical Sciences .Inclusion criteria were patients with the age of more than 18; ability to swallow the capsule; patients with IBS who their disease are approved by complete medical evaluation. Exclusion criteria include pregnant patients and nursing mothers; patients with any active stomach-interic disease; patients who have to use other drugs that interference with this medication; patients who are disposed to a serious health danger; patients with severe allergy to this plant. 90 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 IBS-QOL and IBS-Severity questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110120071N3**
Registration date: **2016-12-29, 1395/10/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-12-29, 1395/10/09

Registrant information

Name
Mohammad Hosein Farzaei
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2016-11-20, 1395/08/30

Expected recruitment end date

2017-02-18, 1395/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the efficacy of Achillea wilhelmsii capsule in irritable bowel syndrome patients:a randomized double blind placebo controlled clinical trial

Public title

Evaluation the efficacy of Achillea wilhelmsii capsule in irritable bowel syndrome 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 ; patients who are not cured with Achillea wilhelmsii during a last month ; Patients who their diseases are approved by complete medical evaluation. Exclusion criteria : pregnant patients and nursing mothers ; patients with any active stomach-interic disease ; patients who have to use other drugs that interference with this medication (such as laxative، antidepressants، opioid and narcotic analgesics) ; 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 ; patients with severe allergy to this plant (dermatitis contact) will be excluded.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kermanshah University of Medical Sciences

Street address
Kermanshah University of Medical Sciences, Kermanshah

City
Kermanshah

Postal code

Approval date
2016-10-19, 1395/07/28

Ethics committee reference number
KUMS.REC.1395.440

Health conditions studied

1

Description of health condition studied
Irritable bowel syndrom

ICD-10 code
K58.9 , K5

ICD-10 code description
Irritable bowel syndrome with diarrhea, Irritable bowel syndrome without diarrhoea

Primary outcomes

1

Description
Diarrhea

Timepoint
Before using the drug-2 weeks after using the drug-30 days after using the drugs

Method of measurement
Based on IBS-QOL and IBS-SEVERITY questionary

2

Description
Constipation

Timepoint
Before using the drug-2 weeks after using the drug-30 days after using the drugs

Method of measurement
Based on IBS-QOL and IBS-SEVERITY questionary

3

Description
Bloat

Timepoint
Before using the drug-2 weeks after using the drug-30 days after using the drugs

Method of measurement
Based on IBS-QOL and IBS-SEVERITY questionary

4

Description
Abdominal pain

Timepoint
Before using the drug-2 weeks after using the drug-30 days after using the drugs

Method of measurement
Based on IBS-QOL and IBS-SEVERITY questionary

Secondary outcomes

1

Description
Photosensivity

Timepoint
Before start use drug-two weeks after use drug-four weeks after use drug

Method of measurement
Based on side effect questionary

2

Description
Digestive problems
Timepoint
Before start use drug-two weeks after use drug-four weeks after use drug
Method of measurement
Based on side effect questionary

Intervention groups

1

Description
Tow capsule (each capsule contain 250mg achillea wilhelmsii) daily for a month in test group.
Category
Treatment - Drugs

2

Description
Tow capsule (each capsule contain 250mg HPMC)daily for a month in placebo group.
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
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Emam khomeini Hospital, Kermanshah University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice – Chancellery of Research, Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Behrooz Hamzeh
Street address
Vice – Chancellery of 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 – Chancellery of 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
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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