

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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 its 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-intestinal 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

Faculty of Pharmacy, Kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3825 0271

##### Email address

mh-farzaee@razi.tums.ac.ir

##### 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 questionnaire

### 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 questionnaire

### 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 questionnaire

### 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 questionnaire

## Secondary outcomes

### 1

#### Description

Photosensitivity

#### Timepoint

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

#### Method of measurement

Based on side effect questionnaire

## 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 questionnaire

## 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

##### Street address

Emam khomeini Hospital, Kermanshah University of Medical Sciences

##### City

Kermanshah

## 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

##### Name of organization / entity

Faculty of pharmacy, Kermanshah University of Medical Sciences

##### Full name of responsible person

Sayed Padide Derakhshande

##### Position

Student of pharmacy

##### Other areas of specialty/work

##### Street address

Faculty of pharmacy, Kermanshah University of Medical Sciences, Kermanshah

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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##### Full name of responsible person

Dr Mohamad Hosein Farzaee

##### Position

Traditional medicine/ PhD

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Faculty of Pharmacy, Kermanshah University of  
Medical Sciences

**Full name of responsible person**

Sayede Padide Derakhshande

**Position**

Student of Pharmacy

**Other areas of specialty/work****Street address**

Faculty of Pharmacy, Kermanshah University of  
Medical Sciences, Kermanshah

**City**

Kermanshah

**Postal code****Phone****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*