

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Effect of Hydroalcoholic Extract of Rose in the Treatment of Chronic Idiopathic Constipation in Patients Referring to Mofateh Clinic in Yasuj

#### Protocol summary

##### Study aim

Determination of the Effect of Rose Hydroalcoholic Extract on the Treatment of Chronic Idiopathic Constipation in Patients Referring to the Mofateh Clinic in Yasuj

##### Design

1. The control group receives lactulose 20 cc twice a day
2. The test group receives the extract of the rose extract at a dose of 20 mg per kg body weight per day in divided doses

##### Settings and conduct

Patients referring to the internal clinic of shahid Mofattah Yasuj

##### Participants/Inclusion and exclusion criteria

Adults with chronic constipation according to Rome 4 criteria with informed consent and no underlying disease such as hypothyroidism-diabetes-celiac lead-poisoning, no structural disease, no constipation treatment before the initial visit

##### Intervention groups

In this study, lactulose is compared as one of the standard treatments for constipation and hydroalcoholic extract of roses.

##### Main outcome variables

Based on the results of the study, if the extract of rose flower extract is effective in the treatment of chronic constipation in adults, it can be used to treat constipation.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190124042481N1**

Registration date: **2019-02-07, 1397/11/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-02-07, 1397/11/18**

Update count: **0**

##### Registration date

2019-02-07, 1397/11/18

##### Registrant information

###### Name

Majid Alamdari

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 74 2233 0163

###### Email address

jokar4132@gmail.com

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2019-01-05, 1397/10/15

##### Expected recruitment end date

2019-05-05, 1398/02/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Hydroalcoholic Extract of Rose in the Treatment of Chronic Idiopathic Constipation in Patients Referring to Mofateh Clinic in Yasuj

##### Public title

Extract of Rose and treatment of constipation

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Adults with chronic constipation according to Rome 4 criteria by obtaining informed consent no underlying condition like diabetes and thyroid, celiac, lead poisoning, the absence of structural disease, Non-constipation treatment before the first visit for inclusion (such as lactulose, etc.)

**Exclusion criteria:**

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

No information

**Sample size**

Target sample size: **150**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization Tool: Use Random Number Tables, Numbers 101-175 Roses Numbers 176 to 250 for lactulose Then these numbers are cluttered onto a page and start by placing a number in the direction above and, accordingly, the drug is assigned to people.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Yasuj University of Medical Sciences

**Street address**

Imam Sajjad Hospital

**City**

yasuj

**Province**

Kohgilouyeh-va-Boyerahmad

**Postal code**

7591994579

**Approval date**

2018-10-13, 1397/07/21

**Ethics committee reference number**

IR.YUMS.REC.1397.113

**Health conditions studied**

**1**

**Description of health condition studied**

Chronic Idiopathic Constipation

**ICD-10 code**

K59.09

**ICD-10 code description**

Other constipation

**Primary outcomes**

**1**

**Description**

People with chronic idiopathic constipation who have 2 or more grade according to Rome 4 criteria

**Timepoint**

All of the above groups meet weekly on a weekly basis: initial visit and diagnosis of days 7, 14, 21 and 28 after the initial visit

**Method of measurement**

Interview and examination of the number and consistency of fecal excretion in week

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Patients with chronic idiopathic constipation treated with hydroalcoholic extract of Roses (which was produced at the Yasuj Medical Science Research Station and prepared as a capsule and dosed with the desired dosage) at a dose of 10 milligrams per body weight twice a day which should be consumed for a month

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Patients with Chronic iodopathic constipation treated with lactulose (Alborz daroo) which should be consumed for a month

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Imam Sajjad Hospital, Shahid Mofateh Clinic

**Full name of responsible person**

Majid Alamdari

**Street address**

Imam Sajjad Hospital  
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yasuj  
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jokar4132@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Yasouj University of Medical Sciences  
**Full name of responsible person**  
Dr. Hossein Mari Oryad  
**Street address**  
Motahari Blvd, Yasouj University of Medical Sciences.Adjutancy of research  
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Yasuj  
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7591741417  
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**Email**  
Oryad.hossein@yums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Yasouj 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**  
Yasouj University of Medical Sciences  
**Full name of responsible person**  
Sajad Hasanzadeh  
**Position**  
Associate professor

**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Internal Medicine  
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## Person responsible for scientific inquiries

#### Contact

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Yasouj University of Medical Sciences  
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Associate professor  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Yasouj University of Medical Sciences  
**Full name of responsible person**  
Majid Alamdari  
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Internal Medicine Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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**Street address**  
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**City**  
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**Province**

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**Phone**

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Only, information about the outcome of the study will be published.

**When the data will become available and for how long**

The publication time after the publication of the results will be in a journal.

**To whom data/document is available**

Anyone who wants to have access to information after publishing in a journal.

**Under which criteria data/document could be used**

It can be used with citation conditions.

**From where data/document is obtainable**

Yasuj University of Medical Sciences / Imam Sajjad Hospital, Yasuj, Iran After publication in a journal can go to the website of the journal. Refer to this email: hasanzadeh\_sajad@yahoo.com

**What processes are involved for a request to access data/document**

After the publication of the study information in a journal, it can immediately access the information.

**Comments**