

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 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

Kohgiluyeh-va-Boyer-Ahmad

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 idiopathic 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Dr. Hossein Mari Oryad
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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
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Person responsible for updating data

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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