

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### A comparative study of effect of Rosa damascena hydroalcoholic extract and polyethylenglychol in treatment of chronic constipation in children older than one year

#### Protocol summary

##### Study aim

In Iranian traditional medicine, Rose is used in the treatment of constipation. In addition to reviewing the available articles, there is no clinical study to confirm the traditional use of this plant in the treatment of constipation. Therefore, the aim of this study was to compare the effect of aqueous-alcoholic extract of rose and polyethylene glycol in the treatment of chronic constipation in children 12 months and up

##### Design

The study is a randomized clinical trial and is conducted in a children's community with functional constipation. All patients with constipation are selected by Pediatrician by obtaining a biography and are enrolled by parents by obtaining consent. Children were randomly assigned into two groups of study, including the intervention group and the control group. Both the control and intervention groups were interviewed weekly after the administration of the drug in terms of the type and consistency of the stool and in terms of the frequency and convenience of disposal. And re-examination. The study is done blindly and randomly

##### Settings and conduct

Pediatric Clinic of Yasouj University of Medical Sciences

##### Participants/Inclusion and exclusion criteria

Children over 12 months of age with chronic constipation with informed consent from parents and lack of underlying illnesses

##### Intervention groups

1. The control group receiving the usual treatment, polyethylene glycol, receives twice a day (every 12 hours) 0.3 g / kg 2. The test group receiving daily rosacea extract with a daily dose of 0.125 g / kg twice daily (every 12 hours)

##### Main outcome variables

Changes in patient's bowel habit

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151217025575N2**

Registration date: **2019-07-31, 1398/05/09**

Registration timing: **retrospective**

Last update: **2019-07-31, 1398/05/09**

Update count: **0**

##### Registration date

2019-07-31, 1398/05/09

##### Registrant information

##### Name

HOSSEIN SADEGHI

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 3322 8944

##### Email address

hossein.sadeghi@yums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Yasuj University of Medical Sciences

##### Expected recruitment start date

2016-02-01, 1394/11/12

##### Expected recruitment end date

2017-02-01, 1395/11/13

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

A comparative study of effect of Rosa damascena hydroalcoholic extract and polyethylenglychol in treatment of chronic constipation in children older than one year

### Public title

Effect of Rosa damascena hydroalcoholic extract and polyethylenglychol in treatment of chronic constipation in childrenr

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age more than 12 months  
Lack of underlying illness  
Parental Satisfaction to Participate in the Study

#### Exclusion criteria:

Uncooperative patients  
Lack of adequate access to patient  
Children with organic reasons of constipation such as Hirschsprung´s disease, spina bifida occulta, hypothyroidism, chronic intestinal pseudo-obstruction, anorectal abnormalities; history of anorectal/colon surgery; non-retentive fecal incontinency  
Taking concomitant medications which could modify bowel habit

### Age

From **1 year** old to **12 years** old

### Gender

Both

### Phase

2

### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **150**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomized allocation with simple sampling method to intervention and controlled groups

### Blinding (investigator's opinion)

Double blinded

### Blinding description

The physician and the evaluator do not have any information about the Prescribed medication

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Yasuj University of Medical Sciences Ethics Committee

##### Street address

Yasuj University of Medical Sciences, Motahari Boulevard, Yasuj Yasuj

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyrahmad

##### Postal code

7591741417

#### Approval date

2015-11-04, 1394/08/13

#### Ethics committee reference number

YUMS.REC.1394.97

## Health conditions studied

### 1

#### Description of health condition studied

Childern with functional constipation

#### ICD-10 code

K59.0

#### ICD-10 code description

Constipation

## Primary outcomes

### 1

#### Description

Frequency of defication per week

#### Timepoint

Every three days to three months

#### Method of measurement

Interviews with parents, Rome 3 standard questionnaire

## Secondary outcomes

### 1

#### Description

Frequency of bulky solid stool per week and adverse effect

#### Timepoint

Every three days to three months

#### Method of measurement

Interviews with parents

## Intervention groups

### 1

#### Description

Control group: Patients will receive .3 mg/kg poly ethylene glycol for two weeks, if successful it will be continued for three months  
ntervention group: Patients

will receive .125 mg/kg poly ethylene glycol for two weeks, if successful it will be continu

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Shaheed Mofateh clinic, Yasuj University of Medical Sciences

**Full name of responsible person**

Hossein Sadeghi

**Street address**

Shaheed Beheshti hospital, Montazeri street. Yasuj

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**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Yasuj University of Medical Sciences

**Full name of responsible person**

Dr Abd Mohammad Moosavi

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**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

personal expenses

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Persons

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Yasuj University of Medical Sciences

**Full name of responsible person**

Hossein sadeghi

**Position**

pediaterist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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**Position**

Associate professor

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Ph.D.

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Hossein Sadeghi

**Position**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Sharing plan

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Confidentiality of the secrets of the patient

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available