

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 children

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-Boyerahmad

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

Children with functional constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Frequency of defecation 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
Intervention 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

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Phone

+98 74 3322 8944

Email

h_sadeghi_m@yahoo.com

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

Street address

Vice chancellor for research, Yasuj University of Medical Sciences, Motahari Boulevard, Yasuj Yasuj

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Phone

+98 74 3322 8944

Email

h_sadeghi_m@yahoo.com

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

Street address

Yasuj University of Medical Sciences, Motahari Boulevard, Yasuj Yasuj

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Phone

+98 74 3322 0165

Fax**Email**

h_sadeghi_m@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

Hossein Sadeghi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Yasuj - Shahid Jalil Ave., Yasouj University of Medical Sciences

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

751411417

Phone

+98 74 3322 8944

Fax

Email

h_sadeghi_m@yahoo.com

Web page address

Fax

Email

h_sadeghi_m@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Hossein Sadeghi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Street address

Yasuj Avenue Shahid Jalil Yasouj University of Medical Sciences

City

Yasuj

Province

Kohgiluyeh-va-Boyer-Ahmad

Postal code

7591741417

Phone

+98 74 3322 8941

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