

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of colon washing and conditioning with low pressured irrigator in treatment of chronic constipation and secondary hemorrhoid on women aged 20-40 years

Protocol summary

Summary

The purpose this clinical trial study is to determine the therapeutic effectiveness of colon washing and its conditional by irrigator (designed by researchers and made by the Dourika factory) with a low pressure (2.5-5 PSI) in the secondary constipation and hemorrhoids in women aged 40 - 20 years. 40 patients with chronic constipation and secondary hemorrhoid, from 22 Bahman hospital, will be randomly assigned into intervention or control group. The intervention group was received a six months colon washing with irrigator but the control group will receive conventional treatment method. Constipation, hemorrhoids, and conditioning parts will be measured through a three points rating scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904074263N1**

Registration date: **2010-09-14, 1389/06/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2010-09-14, 1389/06/23

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Deputy for Education and Research, Gonabad University
Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-03-21, 1390/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of colon washing and conditioning with low pressured irrigator in treatment of chronic constipation and secondary hemorrhoid on women aged 20-40 years

Public title

Treatment of chronic constipation and hemorrhoid with colon washing and its conditioning

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: To be women and have been between 40-20 years old . -inclusion criteria of samples for chronic constipation have been done according to criteria in Table 2. inclusion criteria of hemorrhoid: Any hemorrhoid accompanied by constipation and it has been secondary. Table 1: Rome II criteria for chronic constipation (derived from Johnson Kralstein, 2007) The presence of 2 or more of the following for at least 3

months, which need not be consecutive, in the past 12 months *: - straining during more than 25% of defecations - Lumpy or hard stool more than 25% of defecations - Sensation of incomplete evacuation more than 25% of defecations - Sensation of anorectal obstruction / lockade more than 25% of defecations. - Manual maneuvers to facilitate more than 25% of defecations - Less than three defecations per week * loose stools not present, and criteria are insufficient for irritable bowel Syndrome . The Table from Johanson and Kralstein (2007) 22. Table 2 Rome III criteria for functional constipation: -Two or more of the following for the last 3 months: - straining during at least 25% of defecations - hard or Lumpy stools in at least 25% of defecations - Sensation of incomplete evacuation in at least 25% of defecations - Sense of anorectal obstruction in at least 25% of defecations. - Manual maneuvers to facilitate in at least 25% of defecations - Less than 3 bowel movements per week - loose stools are rarely present without the use of laxatives. criteria for irritable bowel Syndrome are not fulfilled The table derived from Choung, et al, (2007) Exclusion criteria: - no pregnant - the history of cancer disease or other organic diseases (by physician diagnosis), such as (diverticulosis, inflammatory bowel disease, IBD and irritable bowel syndrome, IBS-C), by taking the observation from patient and examination by surgeon general is rule out. - the history of pathologies such as tumors of the colon area, that led to hemorrhoid are rejected,

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences , Sento road

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Postal code

Approval date

2010-08-21, 1389/05/30

Ethics committee reference number

2-30-5-1389

Health conditions studied

1

Description of health condition studied

Chronic constipation and secondary hemorrhoid

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Chronic constipation

Timepoint

6 months

Method of measurement

A rating scale

2

Description

Secondary hemorrhoid

Timepoint

6 months

Method of measurement

A rating scale

3

Description

Ordely defecation

Timepoint

6 months

Method of measurement

A rating scale

Secondary outcomes

empty

Intervention groups

1

Description

Colon washing by irrigator (Duration: 1-3 months, how to use of Irrigator: with teaching by a psychologist and a physician)

Category

Treatment - Other

2

Description

Conditioning (duration 1-6 months, how to use: with doing colon washing precisely and orderly by Irrigator at special time)

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

22 Bahman hospital

Full name of responsible person

Dr Shirin Torabi, Assistant professor

Street address

Women clinic-22 Bahman hospital- Naser Khosro street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Drputy for Education and Research, Gonabad University of Medical Sciences

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Dr Kianmehr

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Drputy for Education and Research, Gonabad University of Medical Sciences , Cento road

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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

Drputy for Education and Research, Gonabad 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

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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