

# 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

Jahanshir Tavakolizadeh

###### Name of organization / entity

Gonabad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 53 3725 5335

###### Email address

dr.tavakolizadeh@gmu.ac.ir

###### 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

#### **City**

Gonabad

#### **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**

Secondry hemorroid

##### **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 irregator (Duration: 1-3 months, how to use of Irregator: 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

##### City

Gonabad

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Drputy for Education and Research, Gonabad University of Medical Sciences

##### Full name of responsible person

Dr Kianmehr

##### Street address

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

##### City

Gonabad

#### 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

Gonabad University of Medical Sciences

#### Full name of responsible person

Dr Ali Mohammadpour

#### Position

Research manager, Assistant Professor

#### Other areas of specialty/work

#### Street address

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

#### City

Gonabad

#### Postal code

9691793718

#### Phone

+98 53 3722 5027

#### Fax

+98 53 3722 3814

#### Email

amohammadpur@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Gonabad University of Medical Sciences

#### Full name of responsible person

Dr Jahanshir Tavakolizadeh

#### Position

Assistant professor

#### Other areas of specialty/work

#### Street address

The board of basic science-Deputy for Education and Research, Gonabad University Medical Sciences, Cento road

#### City

Gonabad

#### Postal code

9691793718

#### Phone

+98 53 3722 5027

#### Fax

+98 53 3722 3814

#### Email

jahanshir\_t@yahoo.com.au

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Gonabad University of Medical Sciences

#### Full name of responsible person

Mr Ali Ekrami

#### Position

Research expert

#### Other areas of specialty/work

#### Street address

Research managemete- Deputy for Education and Research, Gonabad University of Medical Sciences,

Centoroad

**City**

Goabad

**Postal code**

9691793718

**Phone**

+98 53 3722 5027

**Fax**

+98 53 3722 3814

**Email**

**Web page address**

**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*