

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Comparison The Efficacy of Iranian Traditional Aloe Vera based Formula and Poly Ethylene Glycol on adult functional constipation

#### Protocol summary

##### Summary

(1) Objectives: Basic goal: Comparison of The Efficacy of Iranian Traditional Aloe Vera based Formula and Poly Ethylene Glycol on adult functional constipation; Special goals: Effect of Iranian Traditional Aloe Vera based Formula & Poly Ethylene Glycol on frequency of bowel movements per week, straining, stool consistency, sense of incomplete evacuation, need to manually maneuver for evacuation and time of defecation after consuming drug in adults with chronic constipation. (2) Design: Randomized Clinical Trial. (3) Setting and conduct: Patients with chronic functional constipation are referred by gastroenterologist to traditional medicine clinic. Then, patients are divided in two groups: Poly Ethylene Glycol and Traditional Aloe Vera based Formula. In first visit, PhD student of Traditional medicine complete consent form, standard constipation's questionnaire based on ROM III criteria and educate drug instructions to patients. Constipation's questionnaire should be complete again in 14 and 28 days after drug consumption. Patients consume drugs only for first 14 days, and don't consume any drug for second 14 days later (off period). Finally, all data are collected and analyzed statistically. (4) Participants including major eligibility criteria: Inclusion criteria: Age more than 18 years; have chronic functional constipation based on ROM III criteria. Exclusion criteria: Drug induced constipation; Intestinal mechanical or pseudo obstruction; Metabolic & Endocrine disorders; Pregnancy & Lactation; Neurologic & myopathic disorders; IBS; Malignancy; Previous history of GI surgery. (5) Intervention: Intervention group one: Iranian traditional Aloe Vera Based formula, cap: 500 mg, 1-2 cap per day before sleeping with 1 glass of hot water for 14 days and Intervention group two: Poly Ethylene Glycol powder, 15 - 20 gram per day with 1 glass of water/juice, 1 hour after breakfast, for 14 days (6) Main outcome measures (variables): Frequency of defecation per week.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013112915584N1**  
Registration date: **2014-03-01, 1392/12/10**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-03-01, 1392/12/10

##### Registrant information

##### Name

Assie Jokar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3324 3117

##### Email address

arezo02003dr@gmail.com

##### Recruitment status

##### Recruitment complete

##### Funding source

Vice chancellor for research of Iranian Traditional Medicine Faculty of Tehran University of Medical Sciences

##### Expected recruitment start date

2013-12-22, 1392/10/01

##### Expected recruitment end date

2014-09-23, 1393/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Comparison The Efficacy of Iranian Traditional Aloe Vera based Formula and Poly Ethylene Glycol on adult functional constipation

**Public title**

Comparison The Efficacy of Iranian Traditional Aloe Vera based Formula and Poly Ethylene Glycol on adult functional constipation

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Age more than 18 years; have chronic functional constipation based on ROM III criteria.  
Exclusion criteria: Drug induced constipation; Intestinal mechanical or pseudo obstruction; Metabolic & Endocrine disorders; Pregnancy & Lactation; Neurologic & myopathic disorders; IBS; Malignancy; Previous history of GI surgery.

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**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**

Ethics Committee of Tehran University of Medical Sciences

**Street address**

Research Institute for Islamic and Complementary Medicine, Pynia Alley, Lalezarno Ave., Jomhuri Eslami St.

**City**

Tehran

**Postal code****Approval date**

2013-05-27, 1392/03/06

**Ethics committee reference number**

112/پ26/م/ط

**Health conditions studied****1****Description of health condition studied**

Functional chronic constipation

**ICD-10 code**

K59.0

**ICD-10 code description**

Constipation

**Primary outcomes****1****Description**

Frequency of defecation per week

**Timepoint**

0: Before intervention, 14: 14 days after consuming drug, 28: 14 days without any drug (off period)

**Method of measurement**

Questionnaire

**2****Description**

Fecal shape & consistency

**Timepoint**

0: Before intervention, 14: 14 days after consuming drug, 28: 14 days without any drug (off period)

**Method of measurement**

Questionnaire

**3****Description**

Defecation time after drug consumption

**Timepoint**

0: Before intervention, 14: 14 days after consuming drug, 28: 14 days without any drug (off period)

**Method of measurement**

Questionnaire

**4****Description**

Sensation of incomplete evacuation

**Timepoint**

0: Before intervention, 14: 14 days after consuming drug, 28: 14 days without any drug (off period)

**Method of measurement**

Questionnaire

**5****Description**

Straining during defecations

**Timepoint**

0: before intervention, 14: 14 days after using drug, 28:

14 days without any drug (off period)

**Method of measurement**

Questionnaire

**6**

**Description**

Manual maneuvers to facilitate defecations

**Timepoint**

0: Before intervention, 14: 14 days after consuming drug, 28: 14 days without any drug (off period)

**Method of measurement**

Questionnaire

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group 1: Iranian traditional Aloe Vera Based formula, cap: 500 mg, 1-2 cap before sleeping with 1 glass of hot water, during 14 days

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group 2: Poly Ethylene Glycol powder, 15 - 20 gr with 1 glass of water/juice, 1 hour after breakfast meal, during 14 days

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Mostafavian Subspecialty Clinic of Imam Khomeini Hospital

**Full name of responsible person**

Dr Marjan Mokhtare

**Street address**

Imam Khomeini Hospital of Sari

**City**

Sari

**2**

**Recruitment center**

**Name of recruitment center**

Iranian Traditional Medicine Clinic of Buali Sina Hospital

**Full name of responsible person**

Dr Assie Jokar

**Street address**

Buali Sina Hospital of Sari.

**City**

Sari

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research of Iranian Traditional Medicine Faculty of Tehran University of Medica

**Full name of responsible person**

Mohammad Bagher Minaei

**Street address**

Traditional Medicine Faculty of Tehran Medical University; Behesht st., Vahdat Eslami Ave.

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research of Iranian Traditional Medicine Faculty of Tehran University of Medica

**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**

Tehran University of Medical Sciences

**Full name of responsible person**

Assie Jokar

**Position**

PhD student of Iranian Traditional medicine

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**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*