

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of honey milk protocol on constipation severity in acute coronary syndrome patients in coronary care unit

#### Protocol summary

##### Summary

Aim: determining effect of honey milk protocol on constipation severity in acute coronary syndrome patients in coronary care unit. Study design: randomized clinical trial study. Research population: patients with acute coronary syndrome that hospitalized in CCU. Main inclusion criteria: complete consciousness; tend to participate in study. Main exclusion criteria: having not intestinal problems; diabetes; glucose and lactose intolerably; chronic constipation. Sample size: 30 patient in each group of test and control. Intervention: milk honey. Outcomes measures: defecation status of patients from abdominal pain (by visual analog scale), form of feces by Bristol scale and severity of constipation by constipation assessment scale (CAS). Methods: after hospitalization to CCU, initially for each patients completed demographic and defecation status questionnaire. Then patients divided to two group test and control randomly. In test group patients give 150ml low fat (1.5 percent) milk with one spoon table honey (approximately 30 gram) for three time a day for five days period. Control group patients receive routine care. Defecation status of each patients in two group measured daily. Finally compared two group with each other from defecation information.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201309285134N7**  
Registration date: **2013-11-09, 1392/08/18**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-11-09, 1392/08/18

#### Registrant information

##### Name

Ali Fakhr-Movahedi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3365 4192

##### Email address

Alimovi49@semums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Semnan University of Medical Sciences

#### Expected recruitment start date

2013-11-11, 1392/08/20

#### Expected recruitment end date

2014-11-11, 1393/08/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of honey milk protocol on constipation severity in acute coronary syndrome patients in coronary care unit

#### Public title

Effect of milk honey on constipation

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: complete consciousness; Hospitalized patients in coronary care unit (CCU) Exclusion criteria: life threatening conditions; Patients with glucose and lactose intolerance syndrome; Patients with acute diarrhea and habitual consumption of laxatives; Patients

with gastrointestinal problems such as inflammatory bowel syndrome; colostomy; and gastrointestinal malignancies; Diabetic patients; Patients with chronic constipation

#### Age

From **40 years** old to **65 years** old

#### Gender

Both

#### Phase

2

#### 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

Ethical committee of Semnan university of medical sciences, Vice chancellor for research and technol

##### Street address

Vice Chancellor for research and technology of medical sciences, The central headquarters of Semnan university, Basij blvd

##### City

Semnan

##### Postal code

#### Approval date

2013-10-22, 1392/07/30

#### Ethics committee reference number

92/358297

## Health conditions studied

### 1

#### Description of health condition studied

Constipation

#### ICD-10 code

K59.0

#### ICD-10 code description

Change in bowel habit

## Primary outcomes

### 1

#### Description

Constipation severity

#### Timepoint

initial of study, daily for 5 day

#### Method of measurement

Constipation assessment scale (CAS)

### 2

#### Description

Abdominal pain

#### Timepoint

initial of study, daily for 5 day

#### Method of measurement

Visual analog scale (VAS) for pain

### 3

#### Description

feces form

#### Timepoint

Initial of study, daily for 5 day

#### Method of measurement

Bristol scale

## Secondary outcomes

### 1

#### Description

Added at 2017-06-16: Sleep quality

#### Timepoint

Added at 2017-06-16: First and third day

#### Method of measurement

Added at 2017-06-16: Richard-Campbell Sleep Questionnaire

## Intervention groups

### 1

#### Description

Intervention group: milk honey protocol as 150 ml low fat (1.5 percent) milk with one spoon table honey (approximately 30 gram)

#### Category

Prevention

### 2

#### Description

Control group: routine cares in coronary critical unit.

#### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Shahrood Imam Hossein Hospital

**Full name of responsible person**

Dr. Mohammad Hossein Ebrahimi

**Street address**

Imam St.

**City**

Shahrood

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor for research, Semnan university of Medical Sciences

**Full name of responsible person**

Dr. Raheb Ghorbani

**Street address**

Vice Chancellor for research and technology of medical sciences, The cenral headquarters of Semnan university, Basij blvd

**City**

Semnan

**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, Semnan 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**

Semnan university of medical sciences

**Full name of responsible person**

Ali Fakhr-Movahedi

**Position**

Assistant professor/ Faculty member

**Other areas of specialty/work****Street address**

Nursing and allied health school, Semnan university of medical sciences, kilometer 5 of Damghan road

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

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Assistant professor/ Faculty member

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## Person responsible for updating data

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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*