

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### The effect of aloolax Syrup on constipation during pregnancy in pregnant women referred to the midwifery clinic Qom city in 1399

#### Protocol summary

##### Study aim

Effect of aloolax on constipation during pregnancy in pregnant women

##### Design

Clinical trial Randomized, parallel, phase 2-3 with drug and control groups with randomized groups Based on block randomization including 36 pregnant women with constipation

##### Settings and conduct

72 Volunteer patients referring to a clinic, with gestational age more than 14 weeks, with constipation, are selected and after obtaining informed consent randomly divided into experimental and control groups (36 people in each group). In both groups, routine training is provided in the national protocol for combating constipation, including mobility, consumption of high-fiber foods, and drinking fluids. In the case group, Aloolax syrup is also provided free of charge with written consent. Then at the end of each week the questionnaire is completed by the Patient. The duration of syrup consumption and its effect is one month. Excellent improvement is defined by a score of 21 and severe symptoms by a score of 7. Finally, the results before and after the study are compared.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: After the fourth month of pregnancy, No history of hemorrhoids and any internal disease, normal TSH, First pregnancy. Exclusion criteria: Smoking, employed.

##### Intervention groups

Intervention group: Aloolax (Prunus domestica ,Sugar,Rosa damascena, Water) syrup consumption two spoons after breakfast and two spoons after dinner + national protocol routine training. Control group: only routine protocol training.

##### Main outcome variables

Intensity of constipation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200806048323N1**

Registration date: **2020-09-05, 1399/06/15**

Registration timing: **prospective**

Last update: **2020-09-05, 1399/06/15**

Update count: **0**

##### Registration date

2020-09-05, 1399/06/15

##### Registrant information

##### Name

Leila Kazemnejad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 25 3778 0001

##### Email address

l.kazemnejad@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-22, 1399/07/01

##### Expected recruitment end date

2022-03-20, 1400/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of aloolax Syrup on constipation during pregnancy in pregnant women referred to the midwifery clinic Qom city in 1399

#### Public title

The effect of aloolax Syrup on constipation during pregnancy in pregnant women referred to the midwifery clinic Qom city in 1399

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

After the fourth month of pregnancy No history of hemorrhoids and any internal disease Normal TSH First pregnancy

##### Exclusion criteria:

Smoking Employed

#### Age

From **18 years** old to **45 years** old

#### Gender

Female

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **72**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The way to select groups is that they will be assigned to groups based on block randomization. Blocks of size 4 are considered. So we will have six blocks containing AABB, ABAB, BBAA, BABA, ABBA, BAAB. Each block will also be randomly selected using a dice throw. For example, if thrown dice is 3, the BBAA block is considered, and therefore the first two patients are assigned to treatment B and the next two patients to treatment A. The differentiation of each groups is a number extracted from the randomization list and provided to the executor as codes A and B. The dice will be thrown 20 times to complete the assignment of patients to the treatment groups.

#### 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

Organizational Committee of Ethics in Biomedical Research

#### Street address

15 Khordad Blvd., Islamic Azad University, Qom

#### City

Qom

#### Province

Ghoum

#### Postal code

۳۷۱۴۹۶۳۷۴۴

#### Approval date

2020-07-25, 1399/05/04

#### Ethics committee reference number

IR.IAU.QOM.REC.1399.013

## Health conditions studied

### 1

#### Description of health condition studied

constipation

#### ICD-10 code

K59.0

#### ICD-10 code description

Constipation

## Primary outcomes

### 1

#### Description

Intensity of constipation

#### Timepoint

Before the intervention, after a month

#### Method of measurement

Questionnaire Rome 3

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Aloolax syrup two spoons after breakfast and two spoons after dinner for one month+ national protocol routine training.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Group with only country protocol routine training

#### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Qom Midwifery Clinic

**Full name of responsible person**

Leila Kazemnejad

**Street address**

15 Khordad Blvd. Islamic Azad University, Qom

**City**

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**Postal code**

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**Phone**

+98 25 3778 0001

**Email**

L.Kazemnejad@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Leila Kazemnejad

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15 Khordad Blvd. Islamic Azad University, Qom

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**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Booali Daroo pharmaceutical company

**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**

Industry

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Leila Kazemnejad

**Position**

Science Committee

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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## Person responsible for scientific inquiries

### Contact

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Islamic Azad University

**Full name of responsible person**

Leila Kazemnejad

**Position**

Science Committee

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Master

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## Person responsible for updating data

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**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**

Undecided - It is not yet known if there will be 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