

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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 updating data

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Fax**Email**

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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