Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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Iran (Islamic Republic of)
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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
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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

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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
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Science Committee
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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