Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The efficacy of cassia fistula syrup on constipation in pregnant women

Protocol summary

Study aim
The efficacy of Cassia Fistula syrup on constipation in pregnant women

Design
This study has a control group with parallel design. Sample size, for the error typeI, 5% and power of 80%, in each group was calculated as 22. Considering 20% dropout rate, the final sample size was calculated 35 in each group. Samples were randomly divided into intervention and control groups. permuted block Randomization will be used with block of 4.

Settings and conduct
This study will be carried out on 70 pregnant women referred to Rouhani hospital in Babol, Mazandaran, Iran. The intervention group will use the syrup, in addition to the nutritional and physical activity recommendations. Three days later, if there is no defecation, 25% added to the dose. Patients are checked in one and two weeks and the constipation checklist will be completed. The control group also received nutrition and physical activity recommendations, and the checklists will be completed in the first and second weeks after the start.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 17-35 years. Gestational age 28-40 weeks. constipation was based on the criteria of the study (less than 3 times/week defecation, pain while defecation, stool stiffness). exclusion criteria: high risk pregnancy. The history of inflammatory bowel disease,intestinal surgery,smoking,drug abuse,history of Rheumatologic diseases

Intervention groups
In the intervention group, cassia fistula syrup will be given to 35 women who had a diagnosis of constipation based on the criteria of the study, twice a day for 2weeks, in addition to nutritional and physical activity recommendations. In the control group, 35women who matched with the intervention group received only nutritional and physical activity recommendations

Main outcome variables
The frequency of defecation per week

General information

Reason for update
Because of our patient age ,we want to entering age between 17 to 38

Acronym

IRCT registration information
IRCT registration number: **IRCT20100704004306N11**
Registration date: **2020-02-13, 1398/11/24**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-27, 1399/03/07**
Update count: **1**

Registration date
2020-02-13, 1398/11/24

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-09, 1398/11/20

Expected recruitment end date
2020-05-09, 1399/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The efficacy of cassia fistula syrup on constipation in pregnant women

Public title
The efficacy of cassia fistula syrup on constipation in pregnant women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Satisfaction with entering the study Age between 17and 38 years Gestational age 28-40 weeks Diagnosis of constipation based on study criteria (defecation less than 3 times a week, pain while defecating and stool stiffness)

Exclusion criteria:
High risk pregnancy (twin pregnancy, abortion, placenta previa, preterm labor, fetal anomaly) History of inflammatory bowel disease (Crohn's disease, ulcerative colitis) History of intestinal surgery Smoking and drug abuse Rheumatologic diseases

Age
From **17 years** old to **38 years** old

Gender
Female

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is performed for two groups in blocks of 4. Patients will randomly divide into two groups: intervention 1 and intervention 2 (intervention 1: nutritional and physical activity recommendations and intervention 2: dietary recommendations and physical activity + cassia fistula syrup). Random permuted blocks (blocks containing 4 of A and B) will be prepared and eligible samples will be assigned to two intervention groups. Intervention groups 1 and 2 are each marked with one of the letters A and B, and cards with different quadruple combinations of letters A and B will be produced. Picking up the cards randomly will determine the following 4 patients will be placed in which of the intervention 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
Ethics committee of Babol University of Medical Sciences

Street address
Ganj Afrooz ave. Babol university of Medical Sciences

City
Babol

Province
Mazandaran

Postal code
47176-47745

Approval date
2019-03-03, 1397/12/12

Ethics committee reference number
IR.MUBABOL.REC.1397.058

Health conditions studied

1

Description of health condition studied
Constipation in pregnant wemon

ICD-10 code
K59.0

ICD-10 code description
Constipation

Primary outcomes

1

Description
frequency of defecation per week

Timepoint
Before intervention and one and two week after intervention

Method of measurement
Constipation cheklist

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group (35 pregnant women) will received nutritional and physical activity recommendations. Also, for two weeks,1 tbsp containing 10 cc of the cassia fistula syrup ("Flubel" syrup produced by Sanabel Daru Co.) twice a day will be given. If constipation does not improve, patients can increase the dose of the drug to 30 cc daily and record this amount.

Category
Treatment - Drugs

2

Description
In the control group (35 pregnant women) only nutritional and physical activity recommendations are given.These recommendations include a written text on the need for adequate fluids, fiber foods, and the need for regular daily physical activity.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Rouhani Hospital

Full name of responsible person
Rozhin Tahmasbi

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Babol University of Medical Sciences, Ganj afrooz st, Babol

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Vice Chancellor for research of Babol University of Medical Sciences

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Web page address
http://research.mubabol.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
Babol University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Rozhin tahmasbi

Position
Resident of Obstetrics and Gynecology

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Resident of Obstetrics and Gynecology

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Other areas of specialty/work

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Person responsible for updating data

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Master

Other areas of specialty/work
Reproductive Biology

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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
Yes - There is 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

Title and more details about the data/document
The result will be sharing

When the data will become available and for how long
The results of the study will be published at least one year after sampling and analyzing the data.

To whom data/document is available
Academic researchers can apply to study documents

Under which criteria data/document could be used
Available for systematic review studies

From where data/document is obtainable
Dr. Seyyed Ali Mozaffarpur is responsible for reviewing requests and information. Call: 00989111139105 or email: seyyedali1357@gmail.com

What processes are involved for a request to access data/document
Dr. Seyyed Ali Mozaffarpur is responsible for reviewing requests and information.

Comments