

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 type I, 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 2 weeks, in addition to nutritional and physical activity recommendations. In the control group, 35 women 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

Name

Masoumeh Golsorkhtabar Amiri

Name of organization / entity

Fatemeh-Zahra infertility and Reproductive Health Research center, Babol University of Medical Scien

Country

Iran (Islamic Republic of)

Phone

+98 11 1227 4881

Email address

s.esmaeelzadeh@mubabol.ac.ir

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 17 and 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 women

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 checklist

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group (35 pregnant women) will receive 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

Street address

Babol University of Medical Sciences, Ganj afrooz st,
Babol

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 3227 4481

Fax

+98 11 3227 4480

Email

tahmasebi.r2@gmail.com

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

Street address

Babol University of Medical Sciences, Ganjafrooz
Avenue, Babol

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 3219 4719

Fax

+98 11 3219 4719

Email

info@mubabol.ac.ir

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

Street address

Babol University of Medical Sciences, Ganj farooz
st. Babol

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 3227 4881

Fax

+98 11 3227 4881

Email

tahmasebi.r2@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Rozhin tahmasbi

Position

Resident of Obstetrics and Gynecology

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Street address

Babol University of Medical Sciences,Ganj afrooz
st.,Babol

City

Babol

Province

Mazandaran

Postal code

47176-47745

Phone

+98 11 3227 4480

Fax

+98 11 3227 4480

Email

tahmasebi.r2@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Neda mehdinezhad gorji

Position

Responsible for Research Center

Latest degree

Master

Other areas of specialty/work

Reproductive Biology

Street address

Al-Zahra Reproductive Health and Infertility
Center,Amol babol old road.Babol,Iran

City

Babol

Province

Mazandaran

Postal code

4719173716

Phone

+98 11 3227 4480

Fax

+98 11 3227 4881

Email

n.mahdinejad@yahoo.com

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