

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of probiotic yoghurt on constipation in pregnancy period: a double-blind randomized controlled trial.

Protocol summary

Summary

Objectives: This study aims to determine the effect of probiotic yoghurt on constipation in pregnancy period.
Design: Two parallel arm Randomized Controlled Trial.
Setting and conduct: This study will be conducted in obstetrics clinic of Alzahra and Taleghani hospitals in Tabriz city. Eligible women will be randomly assigned into two groups of 30 subjects with block sizes of 4 and 6. A person from research team not involved in the recruitment and assigning participants will generate allocation sequence using a computerized program. Opaque sealed sequentially numbered envelopes will be used for allocation concealment. Participants including major eligibility criteria: 60 healthy pregnant women aged up to 18 years old who suffering from constipation.
Interventions: The intervention group will receive probiotic yoghurt 100 grams daily in addition to advice about exercise, High-fiber diet and Magnesium hydroxide syrup. The control group will receive ordinary yoghurt 100 grams daily in addition to advice about exercise, High-fiber diet and Magnesium hydroxide syrup. Main outcome measures: The variables of frequency of bowel movements, straining during bowel movements, stool consistency, sensation of incomplete evacuation during defecation, feeling of blockage in the path of defecation, need to be manipulated to facilitate defecation and stool color will be assessed by the constipation questionnaire, respectively at one week before intervention and during the first, second, third, fourth and sixth weeks after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070110324N18**

Registration date: **2014-12-30, 1393/10/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-30, 1393/10/09

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research Department of Tabriz University of Medical Sciences

Expected recruitment start date

2014-12-01, 1393/09/10

Expected recruitment end date

2015-03-30, 1394/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotic yoghurt on constipation in pregnancy period: a double-blind randomized controlled trial.

Public title

The effect of probiotic yoghurt on constipation in pregnancy period

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Healthy pregnant women who suffering from constipation; Up to 18 years old, Singleton pregnancy; Gestational age between 24-28; Having literacy; Willingness to participate in the study Exclusion criteria: Receiving medication for constipation in less than a week before the study; Having brain problems (e.g. epilepsy) according to the individual expression; Having metabolic disease (hypothyroidism), Hirschsprung's disease, spinal injuries, anorectal malformations, inflammatory bowel disease and previous gastrointestinal surgery according to the individual expression; Using Fermented dairy products containing probiotics 2 weeks before the study; Use of antibiotics within 2 weeks prior to the study.

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Nursing & Midwifery Faculty, South Shariati Street

City

Tabriz

Postal code

3417174914

Approval date

2014-08-20, 1393/05/29

Ethics committee reference number

9343

Health conditions studied

1

Description of health condition studied

Constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Frequency of bowel movements

Timepoint

A week before the intervention and within weeks of the first, second , third , fourth and sixth postintervention

Method of measurement

Constipation Questionnaire

2

Description

Straining during bowel movements

Timepoint

A week before the intervention and within weeks of the first, second , third , fourth and sixth postintervention

Method of measurement

Constipation Questionnaire

3

Description

Stool consistency

Timepoint

A week before the intervention and within weeks of the first, second , third , fourth and sixth postintervention

Method of measurement

Constipation Questionnaire

4

Description

Sensation of incomplete evacuation during defecation

Timepoint

A week before the intervention and within weeks of the first, second , third , fourth and sixth postintervention

Method of measurement

Constipation Questionnaire

5

Description

Feeling of blockage in the path of defecation

Timepoint

A week before the intervention and within weeks of the first, second , third , fourth and sixth postintervention

Method of measurement

Constipation Questionnaire

6

Description

Need to be manipulated to facilitate defecation

Timepoint

A week before the intervention and within weeks of the first, second , third , fourth and sixth postintervention

Method of measurement

Constipation Questionnaire

7

Description

Stool color

Timepoint

A week before the intervention and within weeks of the first, second , third , fourth and sixth postintervention

Method of measurement

Constipation Questionnaire

Secondary outcomes

1

Description

The first time of eliminating the symptoms and improvement in constipation

Timepoint

Before intervention, 1, 2 , 3, 4 and 6 weeks after intervention

Method of measurement

Questionnaire

2

Description

Quality of life score

Timepoint

Before intervention and 6 weeks after intervention

Method of measurement

Quality of Life Questionnaire

3

Description

Side Effects

Timepoint

1, 2 , 3, 4 and 6 weeks after intervention

Method of measurement

Questionnaire

4

Description

Patients satisfaction from treatment

Timepoint

1, 2 , 3, 4 and 6 weeks after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group will receive probiotic yogurt 100 gram daily

Category

Treatment - Other

2

Description

The control group will receive ordinary yoghurt 100 grams daily.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospitals

Full name of responsible person

Kolsoum Shokri

Street address

Nursing & Midwifery Faculty, South Shariati Street

City

Tabriz

2

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Kolsoum Shokri

Street address

Nursing & Midwifery Faculty, South Shariati Street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Rashidi Mohammad Reza

Street address

Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Nursing & Midwifery Faculty, Tabriz University of Medical Sciences

Full name of responsible person

Kolsoum Shokri Gezeljeh

Position

MSc student in Midwifery

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Person responsible for updating data**Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty