

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1479 6969

###### Email address

mirghafourvandm@tbzmed.ac.ir

##### 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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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Nursing & Midwifery Faculty

**Full name of responsible person**

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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*