

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Aug 2026

### comparative evaluating the effect of acupressure and reflexology on constipation in pregnant women in health center of birjand

#### Protocol summary

##### Study aim

determining the effect of acupressure and reflexology on constipation in pregnant women in health centers

##### Design

clinical trial with intervention and control group of phase zero randomization on 90 patient

##### Settings and conduct

this study is performed on 90 pregnant women aged 12 to 32 week who meet the inclusion criteria in health centers of birjand city by simple randomization

##### Participants/Inclusion and exclusion criteria

do you have constipation or moderate to high severity meaning someone has a score of 9 on the pregnancy constipation scale in the last three days

##### Intervention groups

group acupressure-group reflexology-controlled

##### Main outcome variables

severe constipation

Iran (Islamic Republic of)

##### Phone

+98 56 3220 0069

##### Email address

fahimejamshidi1366@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-28, 1400/09/07

##### Expected recruitment end date

2021-12-28, 1400/10/07

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

comparative evaluating the effect of acupressure and reflexology on constipation in pregnant women in health center of birjand

##### Public title

comparative evaluating the effect of acupressure and reflexology on constipation in pregnant women

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

single pregnancy you have moderate constipation being in the 12- 32 week of pregnancy no gastrointestinal disease no history of colon surgery no diabetes do not take intestinal stimulant drugs do not take medication that cause or aggravate constipation no hyperthyroidism no anxiety disorders

###### Exclusion criteria:

a score below 9, compared to a constipation test in the last three days

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210626051706N1**

Registration date: **2021-12-20, 1400/09/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-12-20, 1400/09/29**

Update count: **0**

##### Registration date

2021-12-20, 1400/09/29

##### Registrant information

###### Name

fahime jamshidi

###### Name of organization / entity

###### Country

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 90

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

in this study ,among the health centers of birjand city from an area that were cully,socially and economically similar,were selected by available sampling method and then by simple random method one center as an acupressure group , one center as a reflexology group and another center of control group was selected

**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 birjand university of medical sciences

**Street address**

18,5 Pirozi,2GHaffari

**City**

birjand

**Province**

South Khorasan

**Postal code**

97711876411

**Approval date**

2021-02-14, 1399/11/26

**Ethics committee reference number**

lr.bums.REC.1399.504

**Health conditions studied****1****Description of health condition studied**

constipation in pregnancy

**ICD-10 code**

K59.0

**ICD-10 code description**

Constipation

**Primary outcomes****1****Description**

severe constipation

**Timepoint**

before studying the first week ,the second week,the third week,the fourth week

**Method of measurement**

pregnancy constipation questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

the first group of acupressure intervention that massage in two points li11 and st36 by sixty people with a pressure of 3 to 4 kg for 16 minutes 12 times

**Category**

Other

**2****Description**

intervention group 2 reflexology group massage in the area of large and small intestine in the sole of the foot at the rate of 4 to 5 kg per foot for 8 minutes in 12 turns

**Category**

Other

**3****Description**

Control group: has not received any intervention

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Birjand health centers

**Full name of responsible person**

Fahime Gamshidi

**Street address**

18.Pirozi 5.GHafari 2

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9771876411

**Phone**

+98 56 3220 0073

**Email**

Fahimejamshidi1366@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Mohamad Hasan Namaei

**Street address**

18.Pirozi 5,GHafari2

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9771876411

**Phone**

+98 56 3220 0073

**Email**

fahimejamshidi1366@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Birjand 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**

Birjand University of Medical Sciences

**Full name of responsible person**

Fahime Gamshidi

**Position**

Senior nursing student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

18,GHafari2,Pirozi5

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9771876411

**Phone**

+98 56 3220 0073

**Email**

fahimejamshidi1366@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Fahime Gamshidi

**Position**

Senior nursing student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

18,GHafari 2,Pirozi5

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9771876411

**Phone**

+98 56 3220 0073

**Email**

fahimejamshidi1366@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Fahime Gamshidi

**Position**

Senior nursing student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

18,GHafari,Pirozi 5

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9771876411

**Phone**

+98 56 3220 0073

**Email**

fahimejamshidi1366@gmail.com

## Sharing plan

### **Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

### **Study Protocol**

Yes - There is a plan to make this available

### **Statistical Analysis Plan**

Yes - There is a plan to make this available

### **Informed Consent Form**

Yes - There is a plan to make this available

### **Clinical Study Report**

Yes - There is a plan to make this available

### **Analytic Code**

Yes - There is a plan to make this available

### **Data Dictionary**

Yes - There is a plan to make this available

### **Title and more details about the data/document**

all data can be shared after being unidentified

### **When the data will become available and for how long**

access period starts 3 months after printing

### **To whom data/document is available**

university researchers

### **Under which criteria data/document could be used**

there is no condition for access

### **From where data/document is obtainable**

request a personal email

### **What processes are involved for a request to access data/document**

request a personal email

### **Comments**