

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation the effect of Psyllium powder (oral herbal laxative) in prevention of constipation, hemorrhoids and anal fissure during pregnancy in pregnant women (3rd trimester) who will refer to Pregnancy Care Clinics in Shiraz, Iran during 1 year.

Protocol summary

Summary

During gestational period, constipation results from change in diet, decline in physical activity and decrease digestive system activity. Recently, some herbs have been taken into account to deal with this problem. Psyllium is one of these herbs whose effect appears by absorbing of water and providing additional bulk to the stool. This study is conducted to evaluate probable preventive effects of psyllium powder on constipation and occurrence anal fissure and hemorrhoidal disease in pregnant women. So pregnant women who are at the beginning of 3rd trimester of gestational period will be randomly divided into two groups. Group A will be received psyllium powder twice daily and group B will be received placebo (no intervention). All cases will be visited two times. First time in designed to be 45 days after starting the program (receiving psyllium and placebo) and second time, 7 days before predicted delivery date. Both groups will be evaluated on the base of history and physical examination and results will be analyzed.

General information

Acronym

N/A

IRCT registration information

IRCT registration number: **IRCT201212119936N3**

Registration date: **2013-01-15, 1391/10/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-01-15, 1391/10/26

Registrant information

Name

Leila Ghahramani

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1623 5586

Email address

lghahraman@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2010-08-31, 1389/06/09

Expected recruitment end date

2011-08-31, 1390/06/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of Psyllium powder (oral herbal laxative) in prevention of constipation, hemorrhoids and anal fissure during pregnancy in pregnant women (3rd trimester) who will refer to Pregnancy Care Clinics in Shiraz, Iran during 1 year.

Public title

Evaluation the effect of Psyllium powder (oral herbal laxative) in prevention of constipation, hemorrhoids and anal fissure during pregnancy

Purpose

Prevention

Inclusion/Exclusion criteria

pregnant women at the onset of 3rd trimester; age between 20 and 30 years; primi para; negative history of anorectal diseases; absence of signs suggestive of anorectal disease based on clinical examination at baseline.

Age

From **20 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **3136**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences Ethics Committee

Street address

Shiraz University of Medical Sciences, Zand street, Shiraz

City

Shiraz

Postal code**Approval date**

2010-04-21, 1389/02/01

Ethics committee reference number

2220

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

constipation

ICD-10 code

K59.0

ICD-10 code description

constipation

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

Preventing constipation

Timepoint

7 days before the expected date of delivery

Method of measurement

History of less than 3 times defecation per week or uncomfortable defecation is considered as constipation

Secondary outcomes**1****Description**

Fissure

Timepoint

7 days before the expected date of delivery

Method of measurement

History and physical examination

2**Description**

hemorrhoid

Timepoint

7 days before the expected date of delivery

Method of measurement

History and physical examination

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

Psyllium powder will be used twice daily as intervention.

Category

Treatment - Drugs

2**Description**

Control group received placebo which was similar to psyllium powder in appearance and taste. Placebo was prepared by Shiraz School of Pharmacy by the order of Colorectal Research Center. According to pharmacists it had neutral effect considering the objects of the study.

Category

Placebo

Recruitment centers**1****Recruitment center**

Name of recruitment center

Prenatal care clinics in the city of Shiraz, Shiraz
University of Medical Sciences

Full name of responsible person

Leila Ghahramani, MD

Street address

Faghihi hospital, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Vice-Chancellery of Research, Chairman of the
Supreme Council for Research Centers of Shiraz
University

Street address

Shiraz University of Medical Sciences, Shiraz

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Colorectal Research Center, Shiraz University of
Medical Sciences

Full name of responsible person

Leila Ghahramani, MD

Position

Assistant professor of surgery

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Research Center

Full name of responsible person

Leila Ghahramani, MD

Position

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Person responsible for updating data

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Name of organization / entity

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Web page address

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