Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 analized.

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

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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 ofShiraz Universi

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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Full name of responsible person
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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