

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparing the effect of Fennelin and Dimethicone capsule on flatulence rate after cesarean section

Protocol summary

Study aim

Comparing the effect of Fennelin and Dimethicone capsule on flatulence rate after cesarean section

Design

Randomised, controlled, parallel group trial, double blinded design of 80 patients. Randomisation was done by Online randomization service point Sealed Envelope Ltd2019

Settings and conduct

80 eligible women sign a written informed consent form in Al-Zahra Center based on inclusion criteria and after starting the oral feeding with a clear liquid diet (12 to 18 hours after surgery) feel bloated who want to take medicine will be randomly assigned in groups of Fennelin and Dimethicone. After completing the demographic questionnaire, investigator asks them to mark their flatulence rate according to the vas ruler between 0 to 100. Then they receive the drug boxes that have been packaged by the pharmacologist without the awareness of the investigator and the participants in similar and opaque packages, will be explained to them that take one of these capsules with a glass of water every 6 hours and continue to consume them for 24 hours. Also asks them to measure their flatulence rate before taking each capsule and one hour after taking each dose using the vas ruler and record it in Information registration form. The occurrence of any possible side effects during the use of these capsules will be followed through the report of the participants and patient file information, as well as uterine atony and subsequent bleeding

Participants/Inclusion and exclusion criteria

Willingness to participate to the study and sign a written informed consent form, at least ability to read and write, feeling of flatulence, having gestational age of 37-42 weeks

Intervention groups

The Fennel group takes one 30 mg soft capsule of Fennelin every 6 hours for 24 hours. The Dimethicone group takes one 125 mg Dimethicone capsule every 6

hours for 24 hours.

Main outcome variables

Rate of flatulence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160630028717N2**

Registration date: **2021-07-20, 1400/04/29**

Registration timing: **prospective**

Last update: **2021-07-20, 1400/04/29**

Update count: **0**

Registration date

2021-07-20, 1400/04/29

Registrant information

Name

Parvaneh Rezasoltani

Name of organization / entity

Guilan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Fennelin and Dimethicone capsule on flatulence rate after cesarean section

Public title

Comparing the effect of Fennelin and Dimethicone capsule on flatulence rate after cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to participate to the study and sign a written informed consent form At least ability to read and write Feeling of flatulence Having gestational age of 37-42 weeks

Exclusion criteria:

Having contraindication of Fennelin capsule like a history of asthma, seizures, liver disease, cancer, epilepsy and allergic reaction to celery and Fennel according to the mother's declaration and patient file information History of intestinal disease according to the mother's declaration and patient file information

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, by the number of sample volumes required, block randomization with 4 and 6 block sizes will be used to randomize sample in the two groups of Fennelin and Dimethicone. Allocation of samples to groups will be done by online randomization service point Sealed Envelope Ltd. For allocation concealment will be used by Sequentially-Numbered, Opaque, Sealed Envelopes (SNOSE)

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the participants and investigator, person who evaluates the outcome will not be aware of the contents of the drug boxes. the shape of the box containing the capsules(Fennelin and Dimethicone) will be in a same color and size. Each box will be consists of 4, 30 mg of Fennelin capsules or 4 , 125 mg of dimethicone capsules. These boxes will be packed and

tagged A and B letters by pharmacologist. Then these boxes will be delivered to investigator and she will be classified in two groups based on inclusion criteria and block randomization. Also the end of sampling, person who analyst will be aware which of the patients have taken which one of drugs

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Guilan University of Medical Sciences

Street address

Deputy of Research and Technology of Gilan University of Medical Sciences, in front of 17 Shahrivar Hospital, Shahid Siadati Ave., Namjoo St.

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2021-06-30, 1400/04/09

Ethics committee reference number

IR.GUMS.REC.1400.152

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

flatulence rate after cesarean

ICD-10 code

R14

ICD-10 code description

Flatulence and related conditions

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

Rate of flatulence

Timepoint

Before taking each dose of capsules, and one hour after taking them, during 24 h

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The Fennel group receive the box which has 4, 30 mg of Fennelin soft capsule. Each one of capsule consist of Foeniculum vulgare essential oil and standardized based on 27-21 mg of Anethole that made by Barij Essence Pharmaceutical Company. Participants take one Fennelin capsule every 6 hours for 24 hours with a glass of water.

Category

Treatment - Drugs

2

Description

Control group: : The Dimethicone group receive the box which has 4, 125 mg of Dimethicone soft capsulet(D-Gas). Each one of capsule consist of activated Dimethicone that made by Zahravi Pharmaceutical Company. Participants take one Dimethicone capsule every 6 hours for 24 hours with a glass of water

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra educational, research, and remedial center

Full name of responsible person

Marzieh Shahbandari Jourshari

Street address

Al-Zahra educational, research, and remedial center, in front of Azodi stadium, Namjoo Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of Guilan University of Medical Sciences

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice Chancellor for Research and Technology of Guilan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Nursing and Midwifery School of Shahid Dr. Beheshti

Full name of responsible person

Parvaneh Rezasoltani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The results of the data and the main consequences will be shared after the study in format of knowledge translation and exchange report to the university, presentation of reports in domestic or foreign conferences and seminars and publication of article in domestic or foreign scientific-research journals.

When the data will become available and for how long

It is possible to access the study results after the defense and scientific confirmation of the dissertation In a 3 months period

To whom data/document is available

if requested, results will be available to other academic investigators and Vice Chancellor for Research and Technology of Guilan University of Medical Sciences

Under which criteria data/document could be used

The collected data is confidential and will not be disclosed to other persons without the awareness of the Vice Chancellor for Research and Technology of the relevant university

From where data/document is obtainable

To receive the documentation, send the email for update manager

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

After the necessary checks, the desired documentary will be sent by email within one month period

Comments