Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Sep 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 critria 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 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.
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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

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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

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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