

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

The effect of chewing gum on intestinal function in patients after cesarean section

Protocol summary

2017-01-18, 1395/10/29

Summary

This study aims to evaluate the effects of gum chewing, as a kind of pseudo-nutrition, on enhancement of bowel movement and early recovery of post-cesarean ileus. A total of 144 females who undergo cesarean section in Ali Ibn Abitaleb Hospital and hold inclusion criteria will be selected. Those who have preeclampsia, diabetics, heart disease, risks of aspiration and ileus; lack of satisfaction to continue participation; complications after surgery such as atonic uterus; intravenous antibiotic therapy more than 4 doses; complications during surgery, for example to the bladder and bowel; adhesion; length of operation >90 min; use of MgSO₄ after cesarean; and history of malignancy or inflammatory bowel disease will be excluded from the study. After caesarean section, the participants will be randomly allocated into intervention (gum chewing) and control (non-gum chewing) groups. Members of the intervention group will be asked, as soon as they are transferred to the ward, to chew one sugar-free gum four times a day (morning, afternoon, night and before sleep) each for 30 minutes until the first flatus. The controls will start their regimen with mild liquids after hearing the first bowel sound. The main variables in this study are the first defecation time, the time of first post-cesarean flatus, and the time of hearing the first bowel sound.

Registrant information

Name

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Name of organization / entity

Medical University of Zahedan

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of chewing gum on intestinal function in patients after cesarean section

Public title

The effect of chewing gum on intestinal function in patients after cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: women who have undergone caesarean section; Exclusion Criteria: suffering from

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112931168N1**

Registration date: **2017-01-18, 1395/10/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

preeclampsia, diabetics, and heart disease; having risks of aspiration and ileus; lack of patient satisfaction to continue participation; complications after surgery such as atonic uterus; intravenous antibiotic therapy more than 4 doses; complications during surgery, for example to the bladder and bowel; adhesion; length of operation >90 min; use of MgSO4 after cesarean; and history of malignancy or inflammatory bowel disease

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

using table of random numbers for random selection

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Office complex of Zahedan Medical university, Khalij e Fars Blv., Dr.Hesabi Square

City

Zahedan

Postal code

9816743463

Approval date

2014-10-04, 1393/07/12

Ethics committee reference number

1573

Health conditions studied

1

Description of health condition studied

post surgery ileus

ICD-10 code

K56.0

ICD-10 code description

Paralysis of: bowel colon intestine

Primary outcomes

1

Description

the first time of defecation

Timepoint

per 2 hours after cesarean and intervention

Method of measurement

Observation

2

Description

hearing the first bowel sound

Timepoint

per 2 hours after cesarean and intervention

Method of measurement

Observation

3

Description

the first time of gas passing

Timepoint

per 2 hours after cesarean and intervention

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Chewing one sugar-free gum as soon as transferring the patient to ward 4 times (morning, afternoon, evening and bed time)

Category

Prevention

2

Description

Control group: lack of gum chewing, start of diet after hearing the first bowel sound

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali ebne Abitaleb hospital
Full name of responsible person
Street address
Dr.Hesabi square, Khash road
City
Zahedan

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0098543416708
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research of Zahedan University of Medical Sciences
Full name of responsible person
Houshang Rafigh Doust
Street address
Khalij fars blvd. ,Dr Hesabi square, Zahedan
University of Medical Sciences
City
Zahedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Zahedan 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
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Position
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Person responsible for updating data

Contact

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