

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of the effect of acupressure at LI4 point and gum chewing on reactivation of gastrointestinal system after cesarean section: A Parallel Randomized Clinical Trial

Protocol summary

Study aim

Determining the effect of acupressure at LI4 point and gum chewing on the reactivation of the gastrointestinal system after cesarean section

Design

Clinical trial on 105 patients candidates for caesarean section with a control group, double-blind and randomized in a block of 6

Settings and conduct

This study is conducted on patients who are candidates for elective cesarean surgery in Bahar Shahroud Hospital. Acupressure techniques or gum chewing will be done 3 times a day for 20 minutes each time, until the gas is expelled for the first time after cesarean section. Then first-time gas passing after cesarean and the time of defecation for the first time after cesarean will be recorded by an evaluation that is blinded to the type of interventions and groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Elective caesarean section with spinal anesthesia, Healthy condition of the teeth for chewing gum, Not having any lesions in the acupressure area. Exclusion criteria: Lack of consciousness of the patient after the operation, Any type of postoperative complication (patients with more than 1000 ml of postpartum bleeding), Having diarrhea, chronic constipation, gastric reflux and irritable bowel syndrome according to the patient's statement

Intervention groups

In the gum chewing group, after the operation, a pack of gum is provided to the patients and they are asked to chew a piece of gum 3 times a day for at least 20 minutes. In the acupressure group, after the operation, acupressure will be applied 3 times a day for 20 minutes. In the control group, routine measures such as advice on fluid and fiber intake will be performed.

Main outcome variables

First time gas passing after cesarean, The time of defecation for the first time after cesarean section

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200206046395N3**

Registration date: **2024-01-21, 1402/11/01**

Registration timing: **prospective**

Last update: **2024-01-21, 1402/11/01**

Update count: **0**

Registration date

2024-01-21, 1402/11/01

Registrant information

Name

Mobin Mottahedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3233 8090

Email address

mobinmottahedi1372@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-04, 1402/11/15

Expected recruitment end date

2024-06-04, 1403/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of acupressure at LI4 point and gum chewing on reactivation of gastrointestinal system after cesarean section: A Parallel Randomized Clinical Trial

Public title
Comparison of the effect of acupressure at LI4 point and gum chewing on reactivation of gastrointestinal system after cesarean section:

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Elective caesarean section with spinal anesthesia
Healthy condition of the teeth for chewing gum
Not having any lesions in the acupressure area
Ability to read and write in Persian
Being in the 38th to 42nd week of pregnancy
Age 18 to 35 years
Exclusion criteria:
Lack of consciousness of the patient after the operation
Change in anesthesia method (conversion to general anesthesia)
Injury to the intestine and bladder during surgery
Any type of postoperative complication (patients with more than 1000 ml of postpartum bleeding)
Drug and alcohol addiction according to the patient's statements
Having diarrhea, chronic constipation, gastric reflux and irritable bowel syndrome according to the patient's statement
Having language, hearing or vision disorders

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
In the beginning, all the modes in which 3 letters A, B and C can be put together in a block of 6 are produced and a block is selected randomly and by placing among the blocks. The layout pattern in that block is used to allocate patients

Blinding (investigator's opinion)
Double blinded

Blinding description
Due to the nature of the study, it is not possible to blind the study participants. However, measures were taken in collecting information. After the intervention, the person collecting the information will not know the type of the participants' group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahrood University of Medical Sciences
Street address
Shahrood University of Medical Sciences, Haft Tir Square, Shahrood
City
Shahrood
Province
Semnan
Postal code
۳۶۱۴۷۷۳۹۵۵

Approval date
2024-01-10, 1402/10/20

Ethics committee reference number
IR.SHMU.REC.1402.169

Health conditions studied

1

Description of health condition studied
Postoperative Gastrointestinal Tract Dysfunction

ICD-10 code
K55-K64

ICD-10 code description
Other diseases of intestines

Primary outcomes

1

Description
First time gas passing after cesarean

Timepoint
3 times a day, every 8 hours

Method of measurement
Ask the patient

2

Description
The time of defecation for the first time after cesarean section

Timepoint
3 times a day, every 8 hours

Method of measurement

Secondary outcomes

1

Description

The level of pain at the surgical site

Timepoint

3 times a day, every 8 hours

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Severe nausea and vomiting

Timepoint

3 times a day, every 8 hours

Method of measurement

Visual Analogue Scale (VAS)

3

Description

Number of times vomiting

Timepoint

3 times a day, every 8 hours

Method of measurement

Ask the patient

4

Description

Duration of hospitalization

Timepoint

Until the end of discharge from the hospital

Method of measurement

Documents recorded in the patient's file

5

Description

Time to start moving the patient for the first time after cesarean section

Timepoint

3 times a day, every 8 hours

Method of measurement

Ask the patient

Intervention groups

1

Description

Intervention group: In the chewing gum group, a pack of Van brand gum (manufactured by Kurdistan Turpentine Company) containing xylitol is provided to the patients. They are asked to chew a piece of gum for at least 20 minutes 3 times a day before eating breakfast, lunch and dinner.

Category

2

Description

Intervention group: After the operation and after transferring the patients to the ward, acupressure will be performed 3 times a day for 20 minutes. In the acupressure group, the researcher will first wash his hands and warm the hands by touching them, he will ask the patient to be in the desired position, then by finding the LI4 point, he will massage the acupressure slowly and gently. It will be applied for 30 seconds. Gradually this pressure will increase until the patient feels tingling, numbness, heaviness and stretching around the area for 30 seconds. Then it is kept in the same position for 1 minute and gradually after that the pressure will be reduced for 30 seconds. Finally, 30 seconds will be held in the same position and 2 minutes of rest will be applied. Each cycle of this process will last 5 minutes, a total of four alternating 5-minute cycles for both hands will last about 20 minutes.

Category

Treatment - Other

3

Description

Control group: In the control group, routine measures such as recommendations for: 1- liquid consumption, 2- fiber consumption, 3- performing active and passive movements in bed will be performed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahar Hospital

Full name of responsible person

Hossein Bagheri

Street address

Bahar Hospital, in front of the Children's Park, 22 Bahman St, Shahroud

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Shahroud

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3615739111

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mobinmottahedi1372@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hassan Emamiyan

Street address

Shahroud University of Medical Sciences, Haft Tir Square, Shahroud

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mobin Mottahedi

Position

Non-faculty instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only part of the data, such as information related to the main outcome, can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

If necessary, by contacting Mobin Mottahedi and if there is a logical justification for using it for scientific purposes

From where data/document is obtainable

Mobin Mottahedi, Shahrood, Haft Tir Square, Shahrood University of Medical Sciences; Faculty of paramedicine

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

During a phone call or via e-mail and registering the request and stating the reason and purpose, which is logical and approved, up to two weeks

Comments