Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Shahroud University of Medical Sciences, Haft Tir Square, Shahroud

City

Shahroud

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

Ask the patient

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
Treatment - Other

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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3615739111
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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

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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