Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of the effect of using abdominal binder on the amount of vaginal bleeding, pain intensity and mobility after cesarean section

Protocol summary

Study aim
Determining the effect of using a abdominal binder on the amount of vaginal bleeding, pain intensity and mobility after cesarean section

Design
A clinical trial with a control group, parallel, one-way blind, randomized on 184 patients, RAS software will be used for randomization.

Settings and conduct
It will be done in Isfahan hospitals. Eligible people will be selected by easy method and will be randomly assigned to 2 groups of 92 people in blocks of 4 and 6. The data analyzer is unaware of the division of the samples into the control and intervention groups.

Participants/Inclusion and exclusion criteria
No underlying disease, first and second cesarean section, term infant, spinal anesthesia

Intervention groups
In the intervention group, along with routine care, a Paksaman abdominal binder, made in Iran, will be closed after cesarean section with a suitable patient size and a 10% reduction in the circumference of the abdomen, and the control group will receive routine care.

Main outcome variables
Measurement of pain intensity after the intervention every 6 hours for 24 hours, the amount of vaginal bleeding will be measured by calculating the amount of hemoglobin and hematocrit before surgery and 6 and 24 hours after surgery. mobility is measured from a six-minute walk test. Side effects including housing received will be recorded every 6 hours for 24 hours.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20211024052856N1**
Registration date: **2021-11-08, 1400/08/17**
Registration timing: **prospective**

Last update: **2021-11-08, 1400/08/17**
Update count: **0**

Registration date
2021-11-08, 1400/08/17

Registrant information
Name
Fatemeh Anvari
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-11-11, 1400/08/20
Expected recruitment end date
2022-02-09, 1400/11/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of using abdominal binder on the amount of vaginal bleeding, pain intensity and mobility after cesarean section

Public title
Evaluation of the effect of using abdominal binder on the amount of vaginal bleeding, pain intensity and mobility

after cesarean section

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Spinal anesthesia Do not use anti-anxiety and hypnotic drugs and painkillers No underlying disease (neuromuscular disorders, hypertension, kidney disease, heart disease) BMI between 18/5 to 29/5 Term baby Uncomplicated pregnancy such as absence of eclampsia and preeclampsia Do not have any coagulation disorders or use anticoagulants Pfannenstiel incision on the skin and kerr incision on the uterus

Exclusion criteria:

Intolerance of the abdominal binder by the patient Reluctance to continue participating in the study Severe postoperative bleeding Damage to body tissues during cesarean section such as damage to the urinary tract and gastrointestinal tract

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **184**

Randomization (investigator's opinion)

Randomized

Randomization description

Using Random Allocation Software (M. Saghaei),patients were allocated using random blocks of four or six in a 1:1 ration to a group that received abdominal binders or a control group. Group assignments were written down and placed into sequentially numbered opaque envelopes.The allocation was performed by an individual. who was masked to enrollment, data collection.Following cesarean delivery and recording demographic data ,eligible patients' names were written on envelopes; the envelopes were ultimately opened by one of the researchers and patients were then allocated to the intervention or control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data analyzer is unaware of the division of the samples into the control and intervention groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences,Hezar Jarib Street

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Province

Isfehan

Postal code

8174673461

Approval date

2021-09-04, 1400/06/13

Ethics committee reference number

IR.MUI.MED.REC.1400.444

Health conditions studied

1

Description of health condition studied

Delivery by elective cesarean section

ICD-10 code

O82

ICD-10 code description

Encounter for cesarean delivery without indication

Primary outcomes

1

Description

pain

Timepoint

6 hours after intervention, 12 hours after intervention, 18 hours after intervention and 24 hours after intervention

Method of measurement

Visual analog scale

2

Description

The amount of vaginal bleeding

Timepoint

Before intervention, 6 and 24 hours after intervention

Method of measurement

Measurement of hemoglobin and hematocrit using Complete Blood Count test

3

Description

Mobility

Timepoint

12 and 24 hours after the intervention

Method of measurement

Six minute walk test

Secondary outcomes

1

Description
Painkillers
Timepoint
6, 12, 18 and 24 hours after the intervention
Method of measurement
Registration in the questionnaire based on patient records

Intervention groups

1

Description
In the intervention group, in addition to routine care, the patient's abdomen will be closed with a abdominal binder(Paksaman, made in iran) after cesarean section, besides receiving routine care and with regard to a 10% reduction of abdominal circumference. For application of the appropriate abdominal binder, the women’s abdomen measured by standard meter first; then, according to the abdominal circumference, in abdominal circumference fastened for 24 houre after transfer of the patient to the surgery ward. abdominal binder will close in 24 hours. At the end of each shift, the abdomen will be examined and will be open from 12 pm to 6 am.
Category
Treatment - Other

2

Description
Control group: they receive routine care and medication
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti hospital
Full name of responsible person
Fatemeh Anvari
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Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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ah_haghjoo@med.mui.ac.ir
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Soheila Bakhtiari
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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
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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Individual participant data collected for the primary outcome measures
When the data will become available and for how long
After publication for one year
To whom data/document is available
For all people who request data
Under which criteria data/document could be used
It is allowed to perform any analysis on the data, but use

of data for publication is not allowed.

From where data/document is obtainable

Corresponding author of article

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

After requesting the data by email to corresponding author, the data will be sent after a maximum period of one week

Comments