Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of the effects using abdominal binder and routine medical care on clinical outcomes of cesarean section: a randomized controlled trial

Protocol summary

Summary

Objectives: This study aims to determine the effect of using abdominal binder on clinical outcomes of cesarean section. Design: a single blind Randomized Controlled Trial. Setting and conduct: This study will be conducted in hospitals of Gonbad-e kavoos. Eligible women will be selected with convenience sampling and will be randomly assigned into 2 groups of 89 subjects with block sizes of 4 and 6. A person from research team not involved in the recruitment and assigning participants will generate allocation sequence using a computerized program. Opaque sealed sequentially numbered envelops will be used for allocation concealment. Major Inclusion criteria: First or second parity; elective cesarean section and major exclusion criteria: Intolerance of abdominal binder by participant; presence of severe bleeding or bleeding leading to hysterectomy. Interventions: In intervention group will receive an abdominal binder and routine medical care and the control group will receive routine medical cares. The patient's abdomen will be fastened by Paksaman appropriate abdominal binder produced by Iran and with 5% reducing in abdominal circumference. Main outcome measures: before and after intervention, pain will be measured every 6 hours within the first 24 hours, 48 hours after cesarean section and fifth day after intervention. Distress will be evaluated before intervention and 24 and 48 hours after intervention. Hemoglobin and hematocrit levels will be measured before cesarean delivery and 36 hours after intervention. Secondary outcomes include Consumed painkiller 48 hour after intervention, Healing of scar and Satisfaction of participants fifth day after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042521917N2**
Registration date: **2015-06-09, 1394/03/19**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-06-09, 1394/03/19

Registrant information

Name

Sevil Hakimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3479 6770

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effects using abdominal binder and routine medical care on clinical outcomes of cesarean section: a randomized controlled trial

Public title
The effect of using abdominal binder on clinical outcomes of cesarean section

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: First or second parity; elective cesarean section; 18 to 35 years old; having literacy; term pregnancy, singleton and without complicated pregnancy; fannenstiel incision on the skin and Kerr Incision on the uterine; hemoglobin more than 11 g/dl during Pregnancy; no history of substance abuse and smoking; no presence of placenta previa or placenta accreta, Incerta, Percreta at ultrasound; no rupture of membrane more than 6 Hours; permission of gynecologist. Exclusion criteria: Intolerance of abdominal binder by participant; no tendency to continue the study; presence of essential disease based on mother`s report; increasing the duration of surgery more than one hour; simultaneous surgery such as hysterectomy, myomectomy and tubectomy; preeclampsia or eclampsia; presence of severe bleeding or bleeding leading to hysterectomy; presence of hemorrhagic disorders or use of anticoagulant drugs such as heparin or warfarin; tissues damage during cesarean delivery.

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

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **178**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Faculty of Nursing & Midwifery, South Shariati Street

City
Tabriz

Postal code

Approval date
2015-04-13, 1394/01/24

Ethics committee reference number
tbzmed.rec.1394.9

Health conditions studied

1

Description of health condition studied
Cesarean

ICD-10 code
O82.0

ICD-10 code description
Delivery by elective caesarean section

Primary outcomes

1

Description
Pain

Timepoint
Baseline, 6, 12, 18, 24, 48 hours and fifth day after intervention

Method of measurement
Visual Analogous Scale (VAS)

2

Description
Distress

Timepoint
Baseline, 24 and 24 hours after intervention

Method of measurement
Symptom Distress Scale

3

Description
Hemoglobin and hematocrit levels

Timepoint
Baseline and 36 hours after intervention

Method of measurement
hemoglobin and hematocrit

Secondary outcomes

1

Description
Healing of scar

Timepoint
Fifth day after cesarean section

Method of measurement

REEDA scale

2

Description
Consumed painkiller
Timepoint
48 hours after cesarean section
Method of measurement
Calculation of number of consumed painkiller

3

Description
Satisfaction of participants
Timepoint
Fifth day after Cesarean
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: After cesarean delivery, in addition to routine medical cares, the patient's abdomen will be fastened by Paksaman Abdominal Binder produced by Iran For intervention group. For application of appropriate abdominal binder, the women abdomen will be measured by standard meter at first, then, according to the abdomen circumference, abdominal binder with 5% reduction in abdominal circumference will be fastened for two days. At the end of each shift, abdominal binder will be assessed and opened from 10 P.M to 8 A.M.
Category
Treatment - Other

2

Description
The control group will receive routine medical cares and medicine.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada Hospital
Full name of responsible person
Samieh Ghana
Street address
City
Gonbad-e Kavus

2

Recruitment center
Name of recruitment center
Beski Hospital
Full name of responsible person
Samieh Ghana
Street address
City
Gonbad-e Kavus

3

Recruitment center
Name of recruitment center
Khatamolanbia Hospital
Full name of responsible person
Samieh Ghana
Street address
City
Gonbad-e Kavus

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Rashidi Mohammad Reza
Street address
Azadi avenue, Golgasht street,third floor, number 2 central building,research and technology department, Tabriz University of Medical Sciences
City
Tabriz
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, Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Sevil Hakimi
Position
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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