

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 envelopes 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

Email address

hakimis@tbzmed.ac.ir

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

Khatamolania 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

PhD of reproductive health

Other areas of specialty/work**Street address**

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00

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Web page address**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