

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparison of some outcomes of two techniques for expansion of the low transverse uterine incision at cesarean section

Protocol summary

Summary

Objective: Comparison of some outcomes of two techniques for expansion of the low transverse uterine incision at cesarean section Design: Clinical Trial, Single blind, Control with standard technic of surgery, Unicenter Population: All women who are candidate for cesarean section Inclusion criteria: All women with singleton pregnancy and term gestational age who give informed constnt for our research Exclusion criteria: Unknown gestational age, preterm or postterm pregnancy, placenta previa, abruptio placenta, severe hemorrhage before cesarean section, polyhydramnios, connective tissue disorders, estimated fetal weight greater than 4000 gr, uterine atony during or after cesarean section Interventions: Transverse and cephalad cauded blunt expansion of the low transverse uterine incision at cesarean section Main outcome measures: Unwanted extension of uterine incision, Need to blood transfusion, Assessment of intraoperation blood loss At first data form including name, age, gravidity, gestational age, and indication of cesarean section will be completed for all participants .Then they will be assigned to blunt expansion of the uterine incision with transverse traction or cephalad cauded group by quad blocks. Hematocrit will be assessed just before and 6 hours after operation. Surgery will be done under general or spinal anesthesia (based on indication) and all operative procedures will be performed similarly before the uterine incision . A transverse uterine incision in the uterine segment of 1 to 2 cm will be expanded by the designated method. In case group, opening of the lower uterine segment will be created by separation of the index fingers of the surgeon in a cephalad cauded direction along the midline but in the control group the incision will be extended by lateral and upward pressure applied with index fingers.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051533989N1**

Registration date: **2017-06-09, 1396/03/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-09, 1396/03/19

Registrant information

Name

Minoo Yaghmaei

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2590

Email address

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2011-04-03, 1390/01/14

Expected recruitment end date

2012-04-02, 1391/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of some outcomes of two techniques for expansion of the low transverse uterine incision at

cesarean section

Public title

Expansion of the low transverse uterine incision at cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All women with singleton pregnancy, gestational age between 37 to 42 weeks who are candidate for elective or emergency cesarean section and give informed consents for our research. Exclusion criteria: Unknown gestational age, preterm or postterm pregnancy, placenta previa, abruptio placenta, severe hemorrhage before cesarean section, BMI greater than 30, polyhydramnios, connective tissue disorders, estimated fetal weight greater than 4000 gr, uterine atony during or after cesarean section

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 288

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

zahedan University of Medical Sciences

Street address

Dr. Hessabi sq. khaliye Fars Blv.

City

Zahedan

Postal code

Approval date

2011-02-23, 1389/12/04

Ethics committee reference number

89-3678

Health conditions studied

1

Description of health condition studied

Cesarean

ICD-10 code

082

ICD-10 code description

Single delivery by caesarean section

Primary outcomes

1

Description

Unwanted extension of uterine incision to cervix, vagina, upper segment of uterus with need to additional sutures

Timepoint

Just after intervention

Method of measurement

Yes or no with evaluator assessment

2

Description

Need to additional sutures for control of bleeding of uterine incision after repair of that

Timepoint

Just after intervention

Method of measurement

yes or no with evaluator assessment

3

Description

Need to blood transfusion

Timepoint

After intervention

Method of measurement

Yes or no with evaluator assessment

4

Description

More than 10% Hb decrease after cesarean section

Timepoint

After intervention

Method of measurement

Yes or no with medical record assessment

5

Description

Assessment of intraoperation blood loss

Timepoint

Just after intervention

Method of measurement

Assessment by evaluator / mili liter

Secondary outcomes

empty

Intervention groups

1

Description

Case group: After making an incision of 2 cm on lower segment, uterine will be extended in vertical direction to uterine incision with the index fingers.

Category

Treatment - Surgery

2

Description

Control group: After making an incision of 2 cm on lower segment, uterine will be extended in lateral and upward direction with the index fingers.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Aiiebneabitaleb hospital

Full name of responsible person

Mojgan Mokhtari

Street address

Zahedan- Dr Hesabi square

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Hamid Reza Sagheb

Street address

Dr Hesabi Sq, Zahedan

City

Zahedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Mojgan Mokhtari

Position

Obstetrics & Gynecology faculty

Other areas of specialty/work

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Full name of responsible person

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Position

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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