

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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

Mino0 Yaghmaei

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2243 2590

##### Email address

m.yaghmaei@sbm0.ac.ir

#### 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 consent 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

##### Street address

Aliebne Abitaleb Hospital, Hesabi Sq, Zahedan

##### City

Zahedan

##### Postal code

9816743111

##### Phone

+98 54 3329 5570

##### Fax

##### Email

mmokhtari1345@hotmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Zahedan University of Medical Sciences

##### Full name of responsible person

Mojgam Mokhtari

##### Position

Obstetrics & Gynecology faculty

##### Other areas of specialty/work

##### Street address

Aliebne Abitaleb Hospital, Dr Hesabi Sq, Zahedan

##### City

Zahedan

##### Postal code

9816743111

##### Phone

+98 54 3329 5570

##### Fax

##### Email

mmokhtari1345@hotmail.com

##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mino0 Yaghmaei

**Position**

Obstetrics & Gynecology faculty

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

Taleghani Hospital, Arabi Street, Daneshjoo Blv, Evin,  
Tehran

**City**

Tehran

**Postal code**

1985717413

**Phone****Fax****Email**

yaghmaeim@yahoo.comm.yaghmaei@sbm0.ac.ir

**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*