

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of short-term outcomes of two vertical incision in the abdomen and Millard in pregnant women with a previous two time cesarean surgery.

Protocol summary

Summary

1-Goals: Selecting procedure which is associated with minimal complications 2:The study population:Women with a history of more than twotimes cesarean section, candidate for elective Cesarean in Alzahra university Hospital Tabriz 3:Study Designe:Randomized, double-blind contral trial 4- Sample:42 patients with Maylard or vertical section group Intervention 5-Primary outcome measurement: amount of Bleeding, infection,Wound dehiscence severity of pain,Satisfaction from work, based on the need for blood transfusions and number blood gas phase , characterized abdominal incision.In postoperative mothers, the need for analgetics, , and the severity of pain will be determined. Inclusion criteria:Term pregnancy;. history of cesarean section in term pregnancy for more than 2 times; not having an underlying disease such as diabetes or lupus;. not having severe preeclampsia;.no prolonged rupture of membranes (PROM)>= 12 hours, having no oprative bleeding;. Morbid obesity. Exclusion craitria:Midwifery bleeding during surgery ;. including the atonic uterus and placenta accreta ;. placenta percreta ;. need to hysterectomy or ovariectomy ;. need for further explorationduring surgery an underlying disease leading tofutherbleeding ;. such as coagulative disease .Emergency case of midwifery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012102211205N1**

Registration date: **2013-04-22, 1392/02/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-04-22, 1392/02/02

Registrant information

Name

Dr.Zahra Fardiazar

Name of organization / entity

Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Tabriz University of Medical Sciences

Expected recruitment start date

2012-11-05, 1391/08/15

Expected recruitment end date

2013-05-05, 1392/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of short-term outcomes of two vertical incision in the abdomen and Millard in pregnant women with a previous two time cesarean surgery.

Public title

Comparison of short-term outcomes of two vertical incision in the abdomen and Millard in pregnant women

with a previous two time cesarean surgery.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Term pregnancy; . history of cesarean section in term pregnancy for more than 2 times; not having an underlying disease such as diabetes or lupus; . not having severe preeclampsia; . no prolonged rupture of membranes (PROM) >= 12 hours, having no operative bleeding; . Morbid obesity. Exclusion criteria: Midwifery bleeding during surgery ; including the atonic uterus and placenta accreta ; . placenta percreta ; . need to hysterectomy or ovariectomy ; . need for further exploration during surgery an underlying disease leading to further bleeding ; . such as coagulative disease . Emergency case of midwifery.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 84

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double 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

Tabriz University of Medical Sciences, Golgasht avenue

City

Tabriz

Postal code

5138665793

Approval date

2012-10-29, 1391/08/08

Ethics committee reference number

7237/4/5

Health conditions studied**1****Description of health condition studied**

Vertical incision and Millard in Pregnant women

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Bleeding

Timepoint

At the end of the abdominal incision

Method of measurement

Using the site of action of counting gases

Secondary outcomes**1****Description**

Time to move the patient lying down, sitting or walking

Timepoint

Every day until discharge

Method of measurement

Tolerable and intolerable pain and need medication and onset of breastfeeding to infants

2**Description**

pain score

Timepoint

Every 4 hours after surgery until discharge

Method of measurement

Using visual analog scale

Intervention groups**1****Description**

Abdominal vertical incision in 42 patients

Category

Prevention

2**Description**

Millard procedure in 42 patients

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Dr.Zahra Fardiazar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Tabriz University of Medical Sciences

Full name of responsible person

Dr. Alireza Ostad Rahimi

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Tabriz university of medical sciences, Golgasht street, Azadi avenue

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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

Dr.Zahra Fardiazar

Position

Associate

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Women's Reproductive Health Research Center, Tabriz University of Medical Sciences

Full name of responsible person

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associte proffesor

Other areas of specialty/work

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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