

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1553 9161

###### Email address

fardiazar@tbzmed.ac.ir

##### 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

**Street address**

Alzahra hospital, Artesh jonoobi avenue

**City**

Tabriz

**Postal code**

5138665793

**Phone**

+98 41 1553 9161

**Fax**

+98 55412210411

**Email**

fardiazar@tbzmed.ac.ir; ro\_zavarnia@hotmail.com;  
wrhrcenter@gmail.com

**Web page address**

## 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

**Street address**

Tabriz university of medical sciences, Golgasht street,  
Azadi avenue

**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**

Dr.Zahra Fardiazar

**Position**

Associate

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

South Artesh Street Bagh shomal Crossroads Alzahra  
Hospital

**City**

Tabriz

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz uneversity

**Full name of responsible person**

Dr.Zahra Fardiazar

**Position**

Associate

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

Alzahra Hospital, bagh-shomal, Arteshe Jonoubi street

**City**

Tabriz

**Postal code**

5138665793

**Phone**

+98 41 1553 9161

**Fax**

+98 41 1554 1221

**Email**

fardiazar@tbzmed.ac.ir; ro\_zavarnia@hotmail.com;  
wrhrcenter@gmail.com

**Web page address**

## 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**

Dr.Zahra Fardiazar

**Position**

associte proffesor

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

Alzahra hospital,Artesh jonoobi avenue

**City**

Tabriz

**Postal code**

5138665793

**Phone**

+98 41 1553 9161

**Fax**

+98 41 1554 1221

**Email**

fardiazar@tbzmed.ac.ir; ro\_zavarnia@hotmail.com;  
wrhrcenter@gmail.com

**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*