# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

28 Jun 2026

## Surgical staples compared with subcuticular suture for skin closure after cesarean delivery. A Randomized Controlled Trial

## Protocol summary

**Summary**

Surgical staples compared with subcuticular suture for skin closure after cesarean delivery. Design: We conducted a single-center randomized controlled trial that included women with viable pregnancies (≥ 24 weeks) undergoing cesarean delivery at University Hospital, Motahary, Urmia, Iran from Aprill to November 2014. All cesarean types were included - scheduled or unscheduled and primary or repeat cesareans. Women were excluded for the following reasons: inability to obtain informed consent, immune compromising disease (e.g. AIDS), chronic steroid use, diabetic mellitus and BMI≥30. Of 266 women,133 were randomized to staples and 133 women to suture group and compared for wound complications, scar and time of skin closure.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2015061322679N1**
Registration date: **2015-11-18, 1394/08/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2015-11-18, 1394/08/27

**Registrant information**

**Name**

Javad Zeinali

**Name of organization / entity**

Urmia University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 44 3348 3118

**Email address**

zeinali_im@yahoo.com

**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research, Urmia University of Medical Sciences

**Expected recruitment start date**

2014-04-21, 1393/02/01

**Expected recruitment end date**

2014-11-22, 1393/09/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Surgical staples compared with subcuticular suture for skin closure after cesarean delivery. A Randomized Controlled Trial

**Public title**

Surgical staples compared with subcuticular suture for skin closure after cesarean delivery. A Randomized Controlled Trial

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Adult women with 18 years old and viable pregnancies (≥ 24 weeks), emergency or elective cesarean delivery, primary or repeat cesareans; exclusion criteria: inability to obtain informed consent; gestationa age<24weeks; pregnancy with dead fetus; immune compromising disease (e.g. AIDS); chronic steroid use; sever malnutrition; prolong rupture of membrane; suprapubic scar; diabetic mellitus and BMI≥30; drug abuser; fetus macrosomia; heparin or warfarin therapy, coagulopathy.

**Age**
From **1 year** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **266**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**
Patients randomize with concealed envelop colors that choose by them in two groups.

## Secondary Ids

### 1

**Registry name**
**Secondary trial Id**
**Registration date**
2017-11-21, 1396/08/30

### 2

**Registry name**
**Secondary trial Id**
**Registration date**
2017-11-21, 1396/08/30

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Urmia University of Medical Sciences
**Street address**
Resalate Avu - Urmia
**City**
Urmia
**Postal code**
**Approval date**
2014-02-20, 1392/12/01
**Ethics committee reference number**
irumsu.rec.1393.28

## Health conditions studied

### 1

**Description of health condition studied**
cesarean wound complications, such as disruption or infection
**ICD-10 code**
y83-y84
**ICD-10 code description**
y83.8

### 2

**Description of health condition studied**
**ICD-10 code**
**ICD-10 code description**

### 3

**Description of health condition studied**
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
WOUND SCALE
**Timepoint**
6 weeks later
**Method of measurement**
Vancouver Scar Scale

### 2

**Description**
Wound seperation
**Timepoint**
1 and 3 days after surgery
**Method of measurement**
Yes or No

### 3

**Description**
Seroma
**Timepoint**
1 and 3 days after surgery
**Method of measurement**
Yes or No

### 4

**Description**
Time of skin closure
**Timepoint**
At surgery
**Method of measurement**
minute

### 5

**Description**

Pain

**Timepoint**

1 and 3 days after surgery

**Method of measurement**

Score from 0 to 10

## Secondary outcomes

### 1

**Description**

**Timepoint**

**Method of measurement**

### 2

**Description**

**Timepoint**

**Method of measurement**

## Intervention groups

### 1

**Description**

Skin closure with subcuticular suture

**Category**

Prevention

### 2

**Description**

Skin closure with staples

**Category**

Prevention

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Motahari Hospital of Urmia University of Medical Sciences

**Full name of responsible person**

Sahar Asadi

**Street address**

Motahari Hospital, Urmia

**City**

Urmia

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice chancellor for research of Urmia University of Medical Sciences - Dr Mohebi

**Full name of responsible person**

Dr Mohebi

**Street address**

Resalat ave

**City**

Urmia

**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 of Urmia University of Medical Sciences - Dr Mohebi

**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**

Urmia University of Medical Sciences

**Full name of responsible person**

Sahar Asadi

**Position**

Medical Doctor

**Other areas of specialty/work**

**Street address**

Motahari Hospital

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+98 44 3348 3118

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saharasadi03@gmail.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Emam Khomeini Hospital of Urmia University

**Full name of responsible person**

Javad Zeinali

**Position**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

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Subspecialist
**Other areas of specialty/work**
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## 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*