

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 April 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 $BMI \geq 30$. 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

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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; gestational age < 24 weeks; pregnancy with dead fetus; immune compromising disease (e.g. AIDS); chronic steroid use; severe malnutrition; prolonged rupture of membrane; suprapubic scar; diabetic mellitus and $BMI \geq 30$; 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
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Person responsible for updating data

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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