

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of early maternal complications of episiotomy repair in Continuous versus interrupted suturing technique in the primiparous women referring to Niknafs maternity hospital, Rafsanjan 2016-2017

Protocol summary

Summary

This study is a prospective clinical trial that comparing early maternal complications of episiotomy repair in continuous versus interrupted suturing technique in the primiparous women. 140 pregnant women that have Conditions for entry into the study (term Pregnancy (37-42 weeks), singleton pregnancy, vertex presentation, 18-35 years old, BMI <30, non labour dystocia, non large episiotomy, non Instrumental delivery) will randomly divided into two groups each group 70 persons. Group one episiotomy will repair in continuous method and interrupted method in another group. Early maternal complications such as perineal pain and wound healing Will be reviewed at 2 hours after delivery, 3-5 days after delivery, 2 weeks after delivery and 6 weeks after delivery. The results will be announced after completing the sampling and data analyzes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017090635617N1**

Registration date: **2017-09-06, 1396/06/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-06, 1396/06/15

Registrant information

Name

pouran Allahbakhshi nasab

Name of organization / entity

Rafsanjan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

p.allahbakhshi96@gmail.com

Recruitment status

Recruitment complete

Funding source

Rafsanjan University of Medical Sciences

Expected recruitment start date

2017-08-21, 1396/05/30

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of early maternal complications of episiotomy repair in Continuous versus interrupted suturing technique in the primiparous women referring to Niknafs maternity hospital, Rafsanjan 2016-2017

Public title

Comparing episiotomy repair with interrupted method and continuous method.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: term pregnancy(37-42); singleton pregnancy; cephalic presentation; 18-35 years old primiparous; BMI <30. Exclusion criteria: special diet; special disease (anemia, cardiovascular disease, diabetes, immunity disease, liver disease, depression, coagulation disorders, preeclapcia, infectious diseases);

smoking; alcoholism, narcotic drugs, labour dystosia; large episiotomy; postpartum hemorrhage; vacuum; forceps; constant constipation; severe pain and hematoma; fever and chills after childbirth; macrosomia.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

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

Rafsanjan University of Medical Sciences

Street address

Rafsanjan University of Medical Sciences, Imam Ali Blvd.

City

Rafsanjan

Postal code

7717933777

Approval date

2017-08-02, 1396/05/11

Ethics committee reference number

IR. RUMS.REC.1396.90

Health conditions studied

1

Description of health condition studied

Episiotomy

ICD-10 code

O80

ICD-10 code description

Single spontaneous delivery

Primary outcomes

1

Description

Perineal pain

Timepoint

2 hours, 3-5 days, 2 weeks and 6 weeks after delivery

Method of measurement

Visual analog scale

2

Description

Wound infection

Timepoint

2 hours, 3-5 days, 2 weeks and 6 weeks after delivery

Method of measurement

Clinical observation

Secondary outcomes

1

Description

Uncomfortable stitches

Timepoint

2 hours, 3-5 days, 2 weeks and 6 weeks after delivery

Method of measurement

Survey

2

Description

Use of analgesia

Timepoint

2 hours, 3-5 days, 2 weeks and 6 weeks after delivery

Method of measurement

Questionnaire

3

Description

Episiotomy repair time

Timepoint

2 hours, 3-5 days, 2 weeks and 6 weeks after delivery

Method of measurement

Timing

4

Description

Number of pockets

Timepoint

2 hours, 3-5 days, 2 weeks and 6 weeks after delivery

Method of measurement

Counting

Intervention groups

1

Description

intervention group: episiotomy will be repaired with continuous method in four layers: vagina, muscle, subcutaneous and skin without cutting sutures.

Category

Prevention

2

Description

control group: episiotomy will be repaired with interrupted method in four layers in the way vagina continuous lockin, muscle interrupted, subcutaneous continuous and skin interrupted.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Niknafs maternity hospital

Full name of responsible person

Allahbakhshinasab pouran

Street address

Rafsanjan- shohada street

City

Rafsanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Allahbakhshinasab Pouran

Street address

Rafsanjan University of Medical Sciences, Imam Ali Blvd.

City

Rafsanjan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rafsanjan 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

Rafsanjan Faculty of Nursing and Midwifery

Full name of responsible person

Allahbakhshinasab Pouran

Position

Master of Midwifery / Faculty member

Other areas of specialty/work

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Position

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Other areas of specialty/work

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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