

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of early maternal complications of episiotomy repair with Rapid vicryl and chromic catgut in the primiparous women

Protocol summary

Summary

This study is a randomised clinical trial that assessment early maternal morbidity from episiotomy repair with chromic catgut and rapid vicryl. One hundred primiparous women with episiotomy, term gestational age, no specific disease, spontaneous delivery, no labour dystocia and no macrosomia randomly allocated to repair with either, rapid vicryl or chromic catgut (50 each). A group: Chromic catgut. B group: Rapid vicryl. The outcome which will be assessed is perineal pain that measure with a visual analog scale and episiotomy healing that will be measured with reed scale at 24 hours, 3-5 days, 2 weeks and 6 weeks after postpartum.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014061818135N1**
Registration date: **2014-08-02, 1393/05/11**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-02, 1393/05/11

Registrant information

Name

pouran allahbakhshi nasab

Name of organization / entity

Shiraz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4253

Email address

allahbakhshi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

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

Comparison of early maternal complications of episiotomy repair with Rapid vicryl and chromic catgut in the primiparous women

Public title

Comparison of early maternal complications of episiotomy repair with Rapid vicryl and chromic catgut in the primiparous women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: term pregnancy; singleton; Vertex presentation; Age 18-35 years; primiparous; no special diet; lack of specific diseases (anemia, cardiovascular disease, diabetes, immune disorders, liver disease, depression, lack of clotting disorders, preeclampsia and Infectious Diseases); non smoking, alcohol and drugs; BMI less than 27 Exclusion criteria: disorder of delivery (prolonged labor and dystocia steps); extension of episiotomy; heavy bleeding after delivery (over 500 cc); use Vacuum; further manipulating the perineum after childbirth; persistent constipation after childbirth; a serious and long-lasting pain after delivery; hematoma; fever and chills after delivery; 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: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz university of medical sciences

Street address

Central building of Shiraz University of Medical Sciences, Zand Ave, Imam Hossein Square, Shiraz, Iran

City

Shiraz

Postal code

1978 - 71345

Approval date

2014-04-23, 1393/02/03

Ethics committee reference number

7001 -93

Health conditions studied

1

Description of health condition studied

Episiotomy repaire

ICD-10 code

090. 1

ICD-10 code description

Infection of obstetric surgical wound

Primary outcomes

1

Description

Chromic catgut

Timepoint

24 hours postpartum, 3-5 days postpartum, 2weeks postpartum, 6 weeks postpartum

Method of measurement

Qualitative

2

Description

Rapid vicryl

Timepoint

24 hours postpartum, 3-5 days postpartum, 2weeks postpartum, 6 weeks postpartum

Method of measurement

Qualitative

Secondary outcomes

1

Description

Wound healing

Timepoint

24 hours, 3-5 days, 2 weeks, 6 weeks poste partume

Method of measurement

Reeda scale

2

Description

Perineal pain

Timepoint

24 hours postpartum, 3-5 days postpartum, 2weeks postpartum, 6 weeks postpartum

Method of measurement

Visual analog scale

Intervention groups

1

Description

IN intervention group episiotomy repaired with rapid vicryl then aerly maternal morbidity including perineal pain assessment whith visual analog scale and episiotomy wound healing assessment with reeda scale in 24 hours postpartum, 3-5 days postpartum, 2weeks postpartum and 6 weeks postpartum. Then the incidens of complications compaired with control group.

Category

Prevention

2

Description

In control group episiotomy repaired with choromic catgut then early maternal morbidity including perineal pain assessment with visual anaioag scale and episiotomy wound healing assessment with reeda scale in 24 hours

postpartum, 3-5 days postpartum, 2weeks postpartum and 6 weeks postpartum. Then the incidens of complications compaired with intervention group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Niknafs maternity hospital, Rafsanjan

Full name of responsible person

Pouran allahbakhshi nasab

Street address

Niknafs maternity hospital, shohada avenue,
Rafsanjan, Iran

City

Rafsanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Council of Shiraz University of Medical
Sciences

Full name of responsible person

Sara azima

Street address

Central bilding of medical sciences, Zand avenue,
Shiraz, Iran

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Council of Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Pouran allahbakhshi nasab

Position

Master student

Other areas of specialty/work

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**Person responsible for scientific
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Contact

Name of organization / entity

Faculty of Nursing and Midwifery

Full name of responsible person

Sara azima

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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