Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 choromic catgut and rapid vicryl.One hundred primiparous women with episiotomy, term gestational age, no specific disease, spontaneous delivery, no labour dystocioa and no macrosomia randomly allocated to repair with either, rapid vicryl or choromic catgut(50 each).A group: Choromic catgut. B group: Rapid vicryl. The outcom wich will assessed is perineal pain that measure with a visual analog scale and episiotomy healing that will measured with reeda 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
Shiaz university of medical sciences
Country
Iran (Islamic Republic of)
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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); extention of episiotomy; heavy bleeding after delivery (over 500 cc); use Vacium; 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 anaiog 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
Centeral 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 inquiries

Contact

Name of organization / entity
Faculty of Nursing and Midwifery

Full name of responsible person
Sara azima

Position
Master of Midwifery

Other areas of specialty/work

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Faculty of Nursing and Midwifery, Namazi Square, Shiraz, Iran

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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