

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Sep 2026

Comparison of chromic cutgot and polygalactin 910 and vicryl rapid in episiotomy repair

Protocol summary

Study aim

Selection of suitable suture for restoration of episiotomy to reduce complications, decrease hospitalization and frequent visits, and improve the quality of life of women after Vaginal delivery.

Design

Three arm parallel group Non-Blind Randomized Clinical Trial Study

Settings and conduct

Patients referring to the delivery unit of the Besat Hospital in Sanandaj, who Need Episiotomy repaired due to Vaginal Delivery, are repaired sequentially by chrome-plated gut, polygalactin 910 and fast-grained vicryl "smi made in Belgium" branded by the Exeter Saban Was provided.

Participants/Inclusion and exclusion criteria

Inclusion: All women undergo episiotomy and episiotomy repair procedure Exclusion: Includes patient with diabetes, chronic diseases and collagen vascular disease, low socioeconomic status, and very obese patients (BMI above 35), patients treated with corticosteroids, prolonged labor and prolonged Premature Rupture of Membranes

Intervention groups

Patients allocated to 3 groups with chromic cutgut, polygalactin 910 and fast-absorbent vicryl treatment

Main outcome variables

Episiotomy repair; Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141208020249N5**

Registration date: **2019-02-01, 1397/11/12**

Registration timing: **retrospective**

Last update: **2019-02-01, 1397/11/12**

Update count: **0**

Registration date

2019-02-01, 1397/11/12

Registrant information

Name

Behzad Khalafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3344 9697

Email address

khalafi.behzad70@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

2017-10-11, 1396/07/19

Actual recruitment end date

2018-06-21, 1397/03/31

Trial completion date

2018-06-21, 1397/03/31

Scientific title

Comparison of chromic cutgut and polygalactin 910 and vicryl rapid in episiotomy repair

Public title

Episiotomy repair success with different suture wire

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patient who had episiotomy and requires repair of

episiotomy

Exclusion criteria:
 People with diabetes People with chronic disease People with collagen vascular disease Low socioeconomic conditions BMI above 35 Corticosteroid treatment Prolonged delivery Prolonged premature rupture of embryonic membrane

Age
 No age limit

Gender
 Female

Phase
 N/A

Groups that have been masked
 No information

Sample size
 Target sample size: **120**
 Actual sample size reached: **120**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Three-block randomization methods by using random number tables, patients divided into three groups (chrome-plain cat-gut and poly-galactin 910 and fast-absorbent vikriil).

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
 Ethics committee of Kurdistan University of Medical Sciences

Street address
 pasdaran Blvd, opposite Shadi Hotel, Kurdistan University of Medical Sciences, Sanandaj, Management of Medical Researches and Information. POB 6617713446

City
 sanandaj

Province
 Kurdistan

Postal code
 6617713446

Approval date
 2017-10-10, 1396/07/18

Ethics committee reference number
 IR.MUK.REC.1396/188

Health conditions studied

1

Description of health condition studied

Episiotomy repair

ICD-10 code

O70

ICD-10 code description

Perineal laceration during delivery

Primary outcomes

1

Description

Episiotomy Repair

Timepoint

2, 7, 42 day

Method of measurement

Observation and Examination

2

Description

pain

Timepoint

2, 7, 42 day

Method of measurement

Based on the patient's expression, one to nine (1-3 mild, 4-6 moderate, 7-9 severe)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: suture with chromic cutgut

Category

Treatment - Surgery

2

Description

Intervention group: suture with polygalactin 910

Category

Treatment - Surgery

3

Description

Intervention group: suture with vicryl

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Chonur Limoei

Street address

Vakil Crossroad, Besat Hospital, Department of Obstetrics and Gynecology

City

Sanandaj

Province

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Phone

+98 87 3328 2004

Email

lchnour@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Ebrahim Ghaderi

Street address

Sanandaj, Kurdistan University of Medical Sciences, opposite Shadi Hotel, Kurdistan University of Medical Science, POB 6617713446 Management of medical research and information

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khalafi.behzad70@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sanandaj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Sholeh Shahgheibi

Position

Associate professor of Gny & Obs

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Vakil Crossroad, Besat Hospital, Department of Obstetrics and Gynecology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Behzad Khalafi

Position

Research Associate / Researcher Soldier - General
Physician of Kurdistan University of Medical Sciences

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is from the proposal, raw data and project reports

When the data will become available and for how long

Data is available from the legal system six months after publication for two years

To whom data/document is available

All persons will be able to access the Kurdistan University of Medical Sciences's request to the Kurdistan University of Medical Sciences.

Under which criteria data/document could be used

For legal issues and the need to use data in future studies

From where data/document is obtainable

با ارائه درخواست به معاونت تحقیقات و فناوری و تایید کمیته اخلاق -
دکتر شعله شاه غیبی

What processes are involved for a request to access data/document

After submitting a request to the Kurdistan Research and Technology Dept. of Science and Technology, a call for submission is given.

Comments