

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The comparison of the effectiveness of phenytoin cream with placebo on episiotomy healing in primipara women

Protocol summary

Summary

The aim of this study is effect of Phenytoin cream on episiotomy wound healing in primipara women referring to Kowsar Hospital in Qazvin 2014-2015. Inclusion criteria: The women with 18-35 years old and full term pregnancy, singleton and normal vaginal delivery with episiotomy. Exclusion criteria: Extended Episiotomy, manipulation of the perineum, uterus and cervix. In this double blind clinical trial, 130 primiparous women who met inclusion criteria was randomly allocated one of two groups of 65 each into intervention or control group. The questionnaire provided information on individual and obstetrics in the delivery room is completed. After the episiotomy wound healing researcher in the maternity ward after training on wound care and emphasis on personal hygiene and proper nutrition, Coded medications, including phenytoin cream 1% in sterile tube and povidone-iodine solution, in the intervention group and povidone-iodine solution with placebo cream phenytoin in the control group to be delivered mothers. Participants in the phenytoin group used adequate amount area 2 times daily and povidon iodine solution for 10 days after delivery and in cntrol group group used povidon iodine solution with placebo cream. wound healing was assessed with REEDA scale (redness, edema, ecchymosis, discharge, near the edge of the wound)primarily in 24 hours,5 and 10 days after delivery and in the questionnaire will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510118611N1**

Registration date: **2015-11-09, 1394/08/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-09, 1394/08/18

Registrant information

Name

Hamideh Pakniat

Name of organization / entity

Qazvin University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Sciences

Expected recruitment start date

2015-10-22, 1394/07/30

Expected recruitment end date

2016-02-19, 1394/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effectiveness of phenytoin cream with placebo on episiotomy healing in primipara women

Public title

Effect of Phenytoin cream on incision due to normal vaginal delivery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The women with 18-35 years old and full term pregnancy (37 to 42 weeks) being nulliparous; no specific diseases (cardiovascular; hepatic; renal; diabetes; coagulopathy diseases; anemia); non- obese (BMI<29; according to the same scale); singleton; cephalic presentation; episiotomy on gynecological bed; time of repair less than 30 minutes; episiotomy repair by chromic catgut sutures. exclusion criteria: Hematomas during and after the repair of episiotomy; extended Episiotomy; excessive bleeding after childbirth; manipulation of the perineum, uterus and cervix; prolonged rupture of amniotic sac more than 18 hour; use of assistive devices (vacum during delivery); no smoking and alcohol.

Age

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

Gender

Female

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Qazvin University of Medical Sciences

Street address

Bahonar Blvd, Qazvin, Iran

City

Qazvin

Postal code

4321102589

Approval date

2015-05-27, 1394/03/06

Ethics committee reference number

10740/20/3

Health conditions studied**1****Description of health condition studied**

Disruption of Episiotomy

ICD-10 code

O90.1

ICD-10 code description

Disruption of perineal obstetric wound

Primary outcomes**1****Description**

Episiotomy wound healing

Timepoint

24 hours, 5 and 10 days after delivery

Method of measurement

Reeda scale (redness, edema, ecchymosis, discharge, near the edge of the wound)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: phenytoin sodium cream 1% of the drug distribution company Tehran - Iran and Betadine solution purchased 10% of the pharmaceutical company's medipharm Kish - Iran

Category

Treatment - Drugs

2**Description**

Control group: Placebo phenytoin sodium cream of the drug distribution company Tehran - Iran and Betadine solution purchased 10% of the pharmaceutical company's medipharm Kish - Iran

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kowsar Hospital

Full name of responsible person

Hamideh Pakniat

Street address

Kowsar Hospital, Taleghani St, Qazvin, Iran

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research of Qazvin University of Medical Sciences

Full name of responsible person

Hamideh Pakniat

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Iran, Qazvin, Bahonar Blvd

City

Qazvin

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 Qazvin 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**

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Full name of responsible person

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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