Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 refering 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 cervixe. 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
Country
Iran (Islamic Republic of)
Phone
+98 282242452
Email address
hpakniat@qums.ac.ir

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); singelton; 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 cervixe; 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/د

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
Street address
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
Qazvin University of Medical Sciences
Full name of responsible person
Hamideh Pakniat
Position
Asistant Professor, Department of Obstetrics and Gynecology Qazvin University of Medical Sciences
Other areas of specialty/work
Street address
Bahonar Blvd, Qazvin, Iran
City
Qazvin
Postal code
4321102589
Phone
+98 28 3333 6001
Fax
+98 28 3324 2661
Email
pakniat110@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Hamideh Pakniat
Position
Asistant Professor, Department of Obstetrics and Gynecology
Other areas of specialty/work
Street address
Iran, Qazvin, Bahonar Blvd
City
Qazvin
Postal code
1317634156
Phone
+98 28 3223 6375
Fax
+98 28 3324 2661
Email
pakniat110@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Qazvin University Of Medical Sciences
Full name of responsible person
Hamideh Pakniat
Position
Asistant Professor, Department of Obstetrics and Gynecology
Other areas of specialty/work
Street address
Bahonar Blvd, Qazvin, Iran
City
Qazvin
Postal code
1317634156
Phone
+98 28 3333 6001
Fax
+98 28 3324 2661
Email
pakniat110@yahoo.com
Web page address

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