Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The comparison of the effectiveness of phenytoin cream with povidone iodine solution on episiotomy healing and pain relief in primipara women refering to allzahra medical educatinal hospital in Tabriz 2010.

Protocol summary

Summary

The aim of this study is to compare phenytoin cream and Povidone iodine solutions (intervention group = phenytoin cream + placebo solution, non intervention=povidon iodine solution + placebo cream)on episiotomy wound healing and pain relief in primiparous women in Alzahra Maternity Hospital in 2010. In this double blind clinical trial, 120 primiparous women who met inclusion criteria was randomly allocated into intervention or control group. Participants in the phenytoin group used adequate amount area 1 times daily for ten minutes for 10 days after delivery and in Povidone iodine group did the same application with Povidone Iodine solution. Pain was evaluated with visual analog scale and wound healing was assessed with REEDA scale primarily in 24 hours and 10 days after delivery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108243027N9**
Registration date: **2011-10-09, 1390/07/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-10-09, 1390/07/17

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2010-09-07, 1389/06/16

Expected recruitment end date

2011-02-05, 1389/11/16

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 povidone iodine solution on episiotomy healing and pain relief in primipara women refering to allzahra medical educatinal hospital in Tabriz 2010.

Public title

Effect of Phenytoin cream on episiotomy wound healing and relif pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Full term pregnancy; being nulliparous; no special diet;age 18-35 years; no specific diseases (cardiovascular, hepatic, renal; diabetes; coagulopathy diseases;anemia, no history of skin diseases; persistent constipation and hemorroids); mul-nutrition;not taking specific drugs (such as anticoagulant;anti

depressants;anti epileptic;antibiotics;immuno-suppressive drugs); no smoking and alcohol and drugs; having literacy; non- obese (BMI<29; according to the same scale);anterior fetal presentation;Episiotomy on gynecological bed;Episiotomy repair by chromic catgut sutures after prep and drep using the same techniques and in less than 30 minutes;visible injury or previous surgery in the perineal region;normal pregnancy;subjects' willingness to participate in the study; Exclusion criteria: Hematomas or infection after the delivery; history of perineal and vaginal surgery;mismatch between maternal pelvis and fetal size (based on pelvis examination);disorders in labor (first stage of labor after 14 h;the second stage more than 2 h); prolonged rupture of amniotic sac (more than 18 h); manual placenta removal;manipulation of the perineum; excessive bleeding after childbirth; need for neonated resuscitation; extended Episiotomy;use of delivery aids;non- persistent use of drugs; women who decide to withdraw from the research.

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: **120**

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 Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences

City
Tabriz

Postal code

Approval date
2010-08-09, 1389/05/18

Ethics committee reference number
8922

Health conditions studied

1

Description of health condition studied
Perineal wound care

ICD-10 code
O90.1

ICD-10 code description
Disruption of perineal obstetric wound

Primary outcomes

1

Description
Episiotomy wound healing

Timepoint
24 hours and 10 days after delivery

Method of measurement
REED SCALE (Redness, echimosses, edema discharge, aproximation)

Secondary outcomes

1

Description
Episiotomy pain relief

Timepoint
24 hours and 10 days after intervention

Method of measurement
VAS scale(vissual analog scale)

Intervention groups

1

Description
Intervention group 1: phenytoin cream + placebo solution

Category
Treatment - Drugs

2

Description
Intervention group2: povidon iodine solution + placebo cream

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra hospital

Full name of responsible person
Street address
City
تبریز

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy of Tabriz university of Medical Sciences
Full name of responsible person
Dr Rashidi
Street address
Research Deputy of Tabriz university of Medical Sciences, Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Deputy of Tabriz 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

Person responsible for scientific inquiries

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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