

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The comparison of the effectiveness of phenytoin cream with povidone iodine solution on episiotomy healing and pain relief in primipara women referring to allzahra medical educational 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=povidone 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 were 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

Name

Fahimeh Sehhatie Shafaie

Name of organization / entity

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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 referring to allzahra medical educational hospital in Tabriz 2010.

Public title

Effect of Phenytoin cream on episiotomy wound healing and relief 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 hemorrhoids); mal-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

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Fahimeh Sehhatie Shafaie

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Other areas of specialty/work

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