

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Effect of the phenytoin cream in comparison with placebo on episiotomy healing and pain reduction in woman with vaginal delivery

Protocol summary

Summary

The project is a double blind clinical trial with 2 group, with purpose is assessment effect of phenytoin cream on healing and reduce of pain of episiotomy incision on mothers with vaginal delivery. The count of sample in each group is 37 person which for increase of the validity of project and falling the samples 45 person estimated. mothers with 18 to 35 years old with first delivery without special disease and using special drugs where include in the project, in 2 group on treatment with 1%phenytoin cream and group with Oserin cream as a placebo. After 10 days assessment of episiotomy healing would be done with REEDA scale 10 and 20 days after delivery by researcher. Pain in 10 and 20 day after delivery would be assessed with visual analog scale and comparison between two groups will be done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080835575N1**

Registration date: **2017-08-20, 1396/05/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-20, 1396/05/29

Registrant information

Name

Samane Azimi Souteh

Name of organization / entity

Sabzevar University of Medical Sciens

Country

Iran (Islamic Republic of)

Phone

+98 11 3565 9111

Email address

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Recruitment status

Recruitment complete

Funding source

Governmental, Vice chancellor for research, Sabzevar University of Medical Science

Expected recruitment start date

2017-08-16, 1396/05/25

Expected recruitment end date

2017-12-16, 1396/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of the phenytoin cream in comparison with placebo on episiotomy healing and pain reduction in woman with vaginal delivery

Public title

Effect of the phenytoin cream on episiotomy healing and pain reduction

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria : mothers with a term delivery ; women with vaginal delivery and episiotomy incision ; 1 or 2 degree episiotomy incision: not very deep incision ; supporting equipment's like vacuum were not used in delivery process ; a Medio lateral episiotomy incision ; mothers who are not malnutrition or on specific diet ; first pregnancy ; age between 18 years old until 35 ; not having premature rupture of the membranes (PROM) >18 hr.; not having special disease (anemia , cardiovascular disease, diabetes mellitus, immune

disease, liver disease, depression) ; not smoking or drug user ; ability to read and write ; not being obsess (BMI < 29) exclusion criteria: use special drugs like corticosteroid ,anticoagulant, immune system suppressors, wide spectrum antibiotics, anti-histamines, Ca antagonist, chemotherapy and radiotherapy, narcotics ; second repairs after delivery; long time delivery or extreme bleeding after delivery ; obstetrician problems like eclampsia, preeclampsia, placenta Previa, twin or triplet pregnancy , coryoamnionitis. meccunial membranes, polyhidrameniosis ; mothers with infections, abscess and hematoma in perinea

Age

From **17 years** old to **34 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

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 Sabzevar University of Medical Science

Street address

Khorasan Razavi, Sabzevar

City

Sabzevar

Postal code**Approval date**

2017-07-18, 1396/04/27

Ethics committee reference number

ir.medsab.rec 1396.23

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

episiotomy

ICD-10 code

090.1

ICD-10 code description

complication disruption of episiotomy

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

healing - sevierity of pain

Timepoint

10 and 20 days after intervention begining

Method of measurement

REEDA scale for healing- VISUAL ANALOG SCALE for sevierity

Secondary outcomes**1****Description**

dehiscence of insicion- scar lenght

Timepoint

10 and 20 days after begining of intervention

Method of measurement

percent of second reparation- centimeter

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

Interventional group : Phenytoin 1% Cream

Category

Treatment - Drugs

2**Description**

Control group: Osserin Cream(placebo)

Category

Placebo

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

Mobini Hospital

Full name of responsible person

Samane Azimi Souteh

Street address**City**

Sabzevar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Sabzevar University of Medical sciences

Full name of responsible person

Elham Bashtani

Street address

Sabzevar University of Medical Sciences

City

Sabzevar

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, Sabzevar 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**

Research and investigation committee

Full name of responsible person

Masome Haghighi

Position

Research manager

Other areas of specialty/work**Street address**

Central office of University

City

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Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Mobini hospital

Full name of responsible person

Doctor Behnaz Sovizi

Position

Gynecologist

Other areas of specialty/work**Street address**

Sabzevar, Mobini hospital

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Person responsible for updating data

Contact**Name of organization / entity**

Sabzevar University of Medical Science

Full name of responsible person

Samane Azimi Souteh

Position

Student

Other areas of specialty/work**Street address****City**

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samaneazimi79@yahoo.com ; Azimis1@medsab.ac.ir

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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