

# 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

azimis1@medsab.ac.ir

###### 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 beginning

**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 beginning 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

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### 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

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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*