

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluating the effect of Verbascum Thapsus cream on perineal pain intensity and episiotomy healing in primiparous women

#### Protocol summary

##### Summary

The aim of this study is evaluating the effect of the Verbascum Thapsus cream on the perineal pain and episiotomy healing. This double blind clinical trial study is performed on the 100 women who have been inclusion and exclusion criteria for this study. Qualified women are arranged in two groups randomly, intervention group (which use Verbascum cream) and control group (which use placebo cream). Two hours after episiotomy, prescribed cream (placebo or Verbascum depending on determined groups) are applied on the suture as much as a finger knuckle (2cm) two times per day, for 10 days. The severity of pain are evaluated by using of pain ruler and the value of Redness, Edema, Ecchymosis, Discharge and Adhesive are assessed via REEDA Scale, before intervention, 24 hours, 3 days and 10 days after intervention for both groups. Then extracted data are analyzed by statistic techniques.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201511123860N15**

Registration date: **2015-12-02, 1394/09/11**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-12-02, 1394/09/11

##### Registrant information

###### Name

Gity Ozgoli

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8820 2512

###### Email address

gozgoli@sbmu.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Vice Chancellor for Research of Shahid Beheshti University of Medical Sciences

###### Expected recruitment start date

2015-11-22, 1394/09/01

###### Expected recruitment end date

2016-01-21, 1394/11/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Evaluating the effect of Verbascum Thapsus cream on perineal pain intensity and episiotomy healing in primiparous women

###### Public title

Effect of Verbascum cream on perineal pain intensity and episiotomy healing

###### Purpose

Supportive

###### Inclusion/Exclusion criteria

Inclusion criteria: primiparous woman; Age between 18 to 35 years; living in the city of Saveh, Iran; At least having the ability to read and write; Non-smoking and drug abuse; Body mass index ranging from 18/5-30; Gestational age between 37 to 42 weeks; Single pregnancy with cephalic presentation; Newborn weight between 2500 to 4000 grams; Normal vaginal delivery without devices; Medio-lateral episiotomy with 4-3 cm

length; Non infant hospitalization in the NICU; No have history of obstetric complications such as (preeclampsia and eclampsia, Gestational diabetes, Placental abruption, chorioamnionitis, premature rupture of membraneous more than 24 hours); No have severe anemia; Disorder of progression in time for the second stage of labor more than 14 hours more than 2 hours for the third stage more than half an hour; Non Diseases affecting wound healing (Chronic systemic disease, pulmonary disease, coagulation disorders, connective tissue, diabetes, anemia, immunodeficiency, hemophilia, malnutrition, mental disorders, renal failure); Consumption of drugs affecting wound healing (glucocorticoids, anti-coagulatives, anti-epileptic, immune system suppressants, antibiotics or chemotherapy agents); No have allergy to herbal drug; Lack of conflict between the family and the severe financial difficulties in recent months. Exclusion criteria: Unwillingness to continue participating in the study; Lack of care for designated days; Do not use ointments regularly and as directed; Allergy to verbasicum cream; Hematoma in the episiotomy after delivery; The need for perineal reconstruction after episiotomy; Fever and postpartum infection; Severe constipation after childbirth during the study; Hemorrhoids or anal fissure after delivery; Use betadine or sitzbath during the study; Having sex in the first 10 days after episiotomy |

**Age**

From **17 years** old to **35 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

**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 School of Pharmacy and Nursing and Midwifery of Shahid Beheshti University of M

**Street address**

School of Nursing and Midwifery, Niayesh Highway, Valiasr St, Tehran, Iran

**City**

Tehran

**Postal code**

1985717443

**Approval date**

2015-08-08, 1394/05/17

**Ethics committee reference number**

sbmu2.rec.1394.78

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

Episiotomy

**ICD-10 code**

O90.1

**ICD-10 code description**

Disruption of perineal obstetric wound

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

wound healing of episiotomy

**Timepoint**

Before intervention, 24 hours after delivery, 3 and 10 days after delivery

**Method of measurement**

REEDA scale

**2****Description**

Pain intensity

**Timepoint**

Before intervention, 24 hours after delivery, 3 and 10 days after delivery

**Method of measurement**

Numerical Analogue Scale

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

Sedative tablets counting

**Timepoint**

10 day after delivery

**Method of measurement**

questionnaire

**2****Description**

common discontent after childbirth

**Timepoint**

10 day after delivery

**Method of measurement**

questionnaire

## Intervention groups

### 1

#### Description

Intervention group: Verbascum cream (produced in Shahid Beheshti pharmacy faculty) is used as much as one finger amount (2cm) on episiotomy wounds twice per day for 10 days.

#### Category

Treatment - Drugs

### 2

#### Description

In control group; placebo cream (produced in Shahid Beheshti pharmacy faculty) uses topically one finger amount (2cm) on episiotomy wounds twice for 10 days

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Fatima Hospital

##### Full name of responsible person

Sahar Taleb

##### Street address

Fatima Hospital, Shahid Naseri Blvd, University Square, Saveh, Iran

##### City

Saveh

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

vice chancellor for research of School of Nursing and Midwifery of Shahid Beheshti University of Med

##### Full name of responsible person

Dr.Mahrokh Dolatian

##### Street address

School of Nursing and Midwifery, Niayesh Highway, Valiasr St, Tehran, Iran

##### City

Tehran

#### 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 School of Nursing and Midwifery of Shahid Beheshti University of Med

#### 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

School of Nursing and Midwifery of Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Gity Ozgoli

##### Position

PHD of Midwifery /Supervisor

##### Other areas of specialty/work

##### Street address

School of Nursing and Midwifery, Niayesh Highway, Valiasr St, Tehran, Iran

##### City

Tehran

##### Postal code

##### Phone

+98 21 8820 2512

##### Fax

##### Email

g.ozgoli@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

School of Nursing and Midwifery of Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Gity Ozgoli

##### Position

PHD of Midwifery

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##### Web page address

**Person responsible for updating data**

**Contact**

**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*