Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the effect of Verbascum Thapsus cream on perineal pain intesity 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 episiotmy, 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 assed 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
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Iran (Islamic Republic of)
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+98 21 8820 2512
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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 intesity 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 memberanous 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 verbascum 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 l

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 Analouge 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
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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