

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### The effect of Horse tail (*Equisetum arvense*) on healing and the pain of episiotomy among primiparous women: A Randomized Controlled Trial

#### Protocol summary

##### Summary

The aim of this study is to determine the effect of Horse tail ointment on healing and the pain from episiotomy wounds in women. In this triple blind clinical trial, 108 healthy primiparous women aged between 18 - 35 with Mediolateral Episiotomy will be allocated into two, Horse tail or placebo ointment, groups using block randomization with allocation ratio 1:1 and block sizes of 4 and 6 were determined with a computerized program. The ointments will be produced by the pharmacist colleague in similar color and will put into similar tubes with no label. A person not involved in sampling and data collection will put the ointment tubes into sequentially numbered sealed opaque envelopes to conceal allocation sequence. After filling in baseline characteristics and measuring the episiotomy incision length, participants will sequentially get the envelopes and will be asked to rub the ointment with her knuckle on the wound every  $12 \pm 2$  hours. The wound pain and healing will be assessed using visual analogue scale (VAS and REEDA scale) before discharge of hospital (before any intervention),  $5 \pm 1$  and  $10 \pm 1$  day after using the ointments. (in lithotomy position). received data analysed statistical methods

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201305277618N5**  
Registration date: **2013-07-29, 1392/05/07**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-07-29, 1392/05/07

#### Registrant information

##### Name

Soheila Bani

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1479 6770

##### Email address

banis@tbzmed.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Tabriz University of Medical Sciences

#### Expected recruitment start date

2013-07-11, 1392/04/20

#### Expected recruitment end date

2013-10-12, 1392/07/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of Horse tail (*Equisetum arvense*) on healing and the pain of episiotomy among primiparous women: A Randomized Controlled Trial

#### Public title

The effect of Horse tail (*Equisetum arvense*) on healing and the pain of episiotomy among primiparous women: A Randomized Controlled Trial

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion Criteria: healthy primiparous woman; having alive fetus; willingness to participate in the study;

mediolateral episiotomy Exclusion criteria: women less than 18 and more than 35 years old; history of impaired wound healing disease, like systemic disease, cardiac, renal, pulmonary, coagulation disorders, immune deficiency, connective tissue disorders, diabetes, haemophilia ; mental illness; Anaemia in pregnancy (haemoglobin less than 11/5); multiple fetus ; macrosomia; malformed fetus; having early postpartum hemorrhage ; extent or large episiotomy (repair length 4-3 cm) ; Instrumental delivery ; manipulation and vaginal exam history after delivery

#### **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: **108**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Triple blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Research deputy, Tabriz University of Medical Sciences

###### **Street address**

Golgasht street

###### **City**

Tabriz

###### **Postal code**

##### **Approval date**

2013-06-10, 1392/03/20

##### **Ethics committee reference number**

9242

### **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**

Episiotomy healing wound

##### **Timepoint**

Before intervention) before discharge of hospital( and 5±1and 10±1 day after intervention

##### **Method of measurement**

REEDA (Redness, Edema, Ecchymosis, Discharge, Approximation)

#### **2**

##### **Description**

Severity of episiotomy pain

##### **Timepoint**

Before intervention) before discharge of hospital( and 5±1and 10±1 day after intervention

##### **Method of measurement**

Visual Analogue Scale (VAS)

### **Secondary outcomes**

#### **1**

##### **Description**

Acetaminophen tablets counting

##### **Timepoint**

Tenth day after delivery

##### **Method of measurement**

Counted tablets

#### **2**

##### **Description**

The frequency of adverse events in the recipient groups of the Horse tail and placebo ointment

##### **Timepoint**

Tenth day after delivery

##### **Method of measurement**

questionnaire

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: Receiving Horsetail ointment3%,rub the ointment with her knucle on the wound every 12±2 hours for 10 day

##### **Category**

Treatment - Drugs

## 2

### Description

Control group:Receiving placebo ointment rub the ointment with her knucle on the wound every 12±2 hours

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Alzahra hospital

##### Full name of responsible person

Asghari khatooni Azam

##### Street address

Faculty of Nursing and Midwifery, South Shariati

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Research deputy of Tabriz university of medical sciences

##### Full name of responsible person

Dr. KazemShakouri

##### Street address

Golgashtst.

##### 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*

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences

### Full name of responsible person

AsgharikhatooniAzam

### Position

MSc student in midwifery

### Other areas of specialty/work

### Street address

Faculty of Nursing and Midwifery, South Shariati

### City

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### Postal code

### Phone

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a.asghari.kh@gmail.com

### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences

#### Full name of responsible person

BaniSoheila

#### Position

Master of science in midwifery

#### Other areas of specialty/work

#### Street address

Faculty of Nursing and Midwifery, South Shariati

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences

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AsgharikhatooniAzam

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MSc student in midwifery

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a.asghari.kh@gmail.com

**Web page address**

*empty*

## **Sharing plan**

**Informed Consent Form**

*empty*

**Deidentified Individual Participant Data Set (IPD)**

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Statistical Analysis Plan**

**Data Dictionary**

*empty*