

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of Hypericum Perforatum (Perforan) on wound healing episiotomy in women

#### Protocol summary

##### Summary

The objective of this study was the effect of Hypericum Perforatum (Perforan) on wound healing of episiotomy. 120 primiparous mothers with singleton pregnancy for whom episiotomy had been done after uncomplicated normal vaginal delivery were randomly allocated into either intervention or control group. Subjects with any acute or chronic systemic diseases, hypersensitivity, severe wound infection at fifth day after delivery or allergy to Hypericum Perforatum derivatives were excluded. Intervention under study was using Hypericum Perforatum ointment (three times a day for to 10 days) and Patients in control group received placebo ointment. Main outcome measures were pain on wound site, wound site edema, wound infection, suppurative secretion, number of remained sutures at fifth and tenth day after delivery, and wound dehiscence.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT201505061557N5**

Registration date: **2015-06-27, 1394/04/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-06-27, 1394/04/06

##### Registrant information

###### Name

Katayon Vakilian

###### Name of organization / entity

Arak University of Medical Sciences and Health Services

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 1417 3502

##### Email address

k\_vakili@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Arak University of Medical Sciences

##### Expected recruitment start date

2014-10-07, 1393/07/15

##### Expected recruitment end date

2015-03-06, 1393/12/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Hypericum Perforatum (Perforan) on wound healing episiotomy in women

##### Public title

Clinical trial the effect of Hypericum Perforatum (Perforan) on wound healing episiotomy in women

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: singleton pregnancy;primiparous; episiotomy Exclusion criteria: severe infection in 5th day after episiotomy; any acute or chronic diseases or allergy to Hypericum Perforatum

##### Age

From **16 years** old to **45 years** old

##### Gender

Female

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 120

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

random allocation

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Arak University of Medical Sciences

##### Street address

Educational Complex campus, Basij Square, Sardasht, arak, Markazi, Iran, Islamic Republic Of

##### City

Arak

##### Postal code

3848176941

#### Approval date

2014-02-03, 1392/11/14

#### Ethics committee reference number

92-158-8

## Health conditions studied

### 1

#### Description of health condition studied

Episiotomy during vaginal delivery

#### ICD-10 code

o90.1

#### ICD-10 code description

Disruption of wound of; episiotomy

## Primary outcomes

### 1

#### Description

pain

#### Timepoint

Before intervention, 5 and 10 day after intervention

## Method of measurement

visual analogue scale

### 2

#### Description

Discharge

#### Timepoint

Before the intervention, 5 and 10 days after the intervention

#### Method of measurement

Presence of suppurative vaginal discharge

### 3

#### Description

remained sutures

#### Timepoint

Before the intervention, 5 and 10 days after the intervention

#### Method of measurement

number of remained sutures

### 4

#### Description

Dehiscence

#### Timepoint

10th day after intervention

#### Method of measurement

Incidence of wound dehiscence

### 5

#### Description

Edema

#### Timepoint

Before the intervention, 5 and 10 days after the intervention

#### Method of measurement

Diameter of edema on wound site in Centimeter

### 6

#### Description

Redness

#### Timepoint

Before the intervention, 5 and 10 days after the intervention

#### Method of measurement

Diameter of redness in millimeter

## Secondary outcomes

### 1

#### Description

Infection

#### Timepoint

Before the intervention, 5 and 10 days after the intervention

#### Method of measurement

Presence of infective discharge and dehiscence of wound

## Intervention groups

### 1

#### Description

intervention group:Hypericum Perforatum (Perforan) ointment, Combined Vaseline with Hypericum Perforatum extracts, 25% concentration, three times daily for 10 days, POURSINA PHARMACEUTICAL COMPANY

#### Category

Prevention

### 2

#### Description

Control group: Vaseline ointment, three times daily for 10 days, POURSINA PHARMACEUTICAL COMPANY

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ayatollah Taleghani Hospital

##### Full name of responsible person

Kobra Abbasinia

##### Street address

Imam Khomeini Street, Ayatollah Taleghani hospital, Arak.

##### City

Arak

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for research of Arak University of Medical Sciences

##### Full name of responsible person

Kobra Abbasinia

##### Street address

Educational Complex campus, Basij Square, Sardasht, arak.

##### City

Arak

#### 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 Arak 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

Arak University of Medical Sciences

##### Full name of responsible person

Kobra Abbasinia

##### Position

Master degree

##### Other areas of specialty/work

##### Street address

Educational Complex campus, Basij Square, Sardasht, arak.

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+98 86 3417 3502

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kobraabbasinya@yahoo.com

##### Web page address

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Kobra Abbasinia

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##### Other areas of specialty/work

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## Person responsible for updating data

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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*