

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparison effect of massage with lavender essence and just massage on intact perineum, episiotomy and perineal laceration in nulliparous women laceration in nulliparous women

#### Protocol summary

##### Summary

Objective : Comparison effect of perineal massage with Lavender Essence and just massage in second stage of labor in nulliparous . Inclusion criteria: nulliparity, cephalic presentation, no complications an underlying disease.The study population: nulliparous women who were admitted for vaginal birth in Taleghany Maternity House.The sample size were 255 . They were placed in massage with Lavender Essence oil , just massage or control group during second stage of labour untile crowning.Rate of intact perineum, episiotomy and degree of laceration were determined.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138802031839N1**  
Registration date: **2012-05-10, 1391/02/21**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-05-10, 1391/02/21

##### Registrant information

##### Name

Mahtab Attarha

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 861417350009

##### Email address

m.attarha@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Deputy of research of Arak Medical Sciences University & Bareej Essence Pharma.Co.

##### Expected recruitment start date

2007-04-04, 1386/01/15

##### Expected recruitment end date

2007-09-06, 1386/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison effect of massage with lavender essence and just massage on intact perineum, episiotomy and perineal laceration in nulliparous women laceration in nulliparous women

##### Public title

Effect of perineal massage in incidence of intact perineum during vaginal birth

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria (Inclusion criteria) - Term Pregnancy (42-38 weeks), nulliparous, singleton pregnancy, vertex presentation, without PROM, placental abruption, CPD, fetal distress,vaginal infections and herpes genitalia and not do Kegl Exercise. Exclusion criteria were as follows: distosia, fetal distress, use of sedative drugs , operative delivery,the mother withdrew from continuing massage - allergies to lavender

##### Age

From **15 years** old to **40 years** old

##### Gender

Female

## Phase

3

## Groups that have been masked

No information

## Sample size

Target sample size: 265

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

##### Street address

38481-769410, Second Floor of Department of Educational affair, Pardis Building Complex, Sardasht Sq. Arak University of Medical Sciences

##### City

Arak

##### Postal code

##### Approval date

2007-04-04, 1386/01/15

##### Ethics committee reference number

235

## Health conditions studied

### 1

#### Description of health condition studied

Intact perineum, Episiotomy and Laceration

#### ICD-10 code

080

#### ICD-10 code description

Pregnancy, childbirth and the puerperium

## Primary outcomes

### 1

#### Description

Intact perineum

#### Timepoint

postpartum

## Method of measurement

With check list: to determine degree of laceration: intacte perineum without any injury

### 2

#### Description

frequency of episiotomy

#### Timepoint

cross sectional

#### Method of measurement

quantitative variables

### 3

#### Description

Intensity of perineal laceration

#### Timepoint

cross sectional

#### Method of measurement

qualitative were changed to quantitative variables

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

intervent group: perineal massage with lavender essence oil, 5-10 drops in 30-60 cc olive as carrier oil by the midwife, in second stage of labour until crowning of infant's head, for 10 minutes

#### Category

Prevention

### 2

#### Description

Intervent group: just perineal massage by the midwife in second stage of labour until crowning of infant's head for ten minutes

#### Category

Prevention

### 3

#### Description

Control group: no intervention

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taleghany Maternity House

##### Full name of responsible person

Mahtab Attarha  
**Street address**  
**City**  
Arak

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Vice Chancellor and Research of Arak University of  
Medical Sciences

**Full name of responsible person**  
dhood Hekmatpoo Phd

**Street address**  
Po Box: 38481-769410, Second Floor of Educational  
Department, Pardis Building Complex Sardasht Sq.  
Arak University of Medical Sciences

**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 and Research of Arak University of  
Medical Sciences

#### Proportion provided by this source

#### 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*

### 2

#### Sponsor

**Name of organization / entity**  
Bareej Essence Pharmacological Co

**Full name of responsible person**  
Reza Bekhradi

**Street address**  
1178, Delijan, Kashan Road

**City**  
Kashan

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Bareej Essence Pharmacological Co

#### Proportion provided by this source

#### 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

Nursing Midwifery Faculty of Arak University of  
Medical Sciences

##### Full name of responsible person

Attarha Mahtab

##### Position

Senior lecturer, Academician

##### Other areas of specialty/work

##### Street address

Vice Chancellor of Arak University of Medical Sciences

##### City

Arak

##### Postal code

##### Phone

+98 86 1417 3516

##### Fax

##### Email

mahtab\_at2004@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Arak Medical Science University and Bareej Essence  
Pharmaco. Co

##### Full name of responsible person

Attarha M, Bekhradi R

##### Position

Academician and Dean of Clinical Research  
Department of Bareej Essence Co

##### Other areas of specialty/work

##### Street address

vice Chancellor of Arak Medical Sciences University

##### City

Arak & Kashan

##### Postal code

##### Phone

+98 86 1417 3516

##### Fax

##### Email

mahtab\_at2004@yahoo.com

##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

Nursing Midwifery Faculty of Arak University of  
Medical Sciences

##### Full name of responsible person

Attarha M

**Position**

**Other areas of specialty/work**

**Street address**

Second Floor, Blue Wing, Nursing Midwifery Faculty,  
Sardasht Building Complex

**City**

Arak

**Postal code**

38481-769410

**Phone**

**Fax**

+98 86 1417 3524

**Email**

m.attarha@arakmu.ac.ir  
mahtab\_at2004@yahoo.com

**Web page address**

## 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*