

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

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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

intervention 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

Intervention 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

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Pharmaco. Co

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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