

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### The effect of lubricating vaginal with natural animal fat on the second stage of labor, frequency of episiotomy and preineal laceration in primiparous women

#### Protocol summary

##### Study aim

The effect of lubricating vaginal with natural animal fat on the second stage of labor, frequency of episiotomy and preineal laceration in primiparous women

##### Design

The study is a clinical trial performed 129 people and groups of 43 people, two intervention and one control groups.

##### Settings and conduct

The study was conducted on population referred to Shahid Beheshti hospital in Abadan ; these patents were first evaluated by demographic and fertility questionnaire and voluntarily entered the study. Subjects were given a duck fat and lubricant gel and the control group did not receive medication.

##### Participants/Inclusion and exclusion criteria

include criteria: Age 18-35 years, singleton and nulliparous pregnancy, gestational age 37-42 weeks according to ultrasound of the first 3 months of pregnancy or LMP, cephalic presentation, perineal length 3-5 cm uninclud criteria: High fever, Prolonged rupture of the amniotic sac, abruption, FHR drop, Vaginal bleeding, perceptive delivery, OP position, Contraindications to normal delivery and episiotomy, Vaginal infections and genital herpes, Chronic maternal disease

##### Intervention groups

Two intervention groups, one group intake duck oil and the other group intake lubricant in the second phase of labor Control group without medication.

##### Main outcome variables

Time The second stage of labor; episiotomy; Perineal laceration

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20200721048154N1**

Registration date: **2020-08-24, 1399/06/03**

Registration timing: **retrospective**

Last update: **2020-08-24, 1399/06/03**

Update count: **0**

#### Registration date

2020-08-24, 1399/06/03

#### Registrant information

##### Name

Mona Matori abdollahi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 5332 9401

##### Email address

mona.2017.sh00@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2020-03-20, 1399/01/01

#### Expected recruitment end date

2020-07-19, 1399/04/29

#### Actual recruitment start date

2020-03-24, 1399/01/05

#### Actual recruitment end date

2020-07-17, 1399/04/27

#### Trial completion date

2020-07-17, 1399/04/27

#### Scientific title

The effect of lubricating vaginal with natural animal fat on the second stage of labor, frequency of episiotomy

and preineal laceration in primiparous women

### Public title

The effect of lubricating vaginal with natural animal fat on the second stage of labor, frequency of episiotomy and preineal laceration in primiparous women

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age 18-35 years single and primiparous pregnancy  
Gestational age 37-42 weeks according to ultrasound of the first 3 months of pregnancy or last menstrual period  
Cephalic presentation Perineal length 5-3 cm

#### Exclusion criteria:

Occurrence of any obstetric complication including high fever, prolonged rupture of the membranes, placental abruption, decreased FHR, vaginal bleeding, and complications that endanger the health of the mother or her baby. participated delivery. Posterior occipital position. Contraindications to natural vaginal delivery and episiotomy. Vaginal infections and genital herpes and chronic disease in the mother.

### Age

From **18 years** old to **35 years** old

### Gender

Female

### Phase

3

### Groups that have been masked

- Participant

### Sample size

Target sample size: **129**

Actual sample size reached: **129**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Simple randomization method and using a table of random numbers in such a way that in case of unit number 1-2-3 samples in the control group, 4-5-6 samples in the intervention group 1 (gel), 7-8-9 samples in the group Intervention 2 (oil)

### Blinding (investigator's opinion)

Single blinded

### Blinding description

Participants after admission to the hospital and having all the inclusion criteria after completing the informed consent form are completely randomly placed in one of the control groups, intervention 1 (gel), intervention 2 (oil) and participants are unaware of the allocation of study.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

##### Street address

No.415/6, Nine Bahar street, Abadan

##### City

Abadan

##### Province

Khuzestan

##### Postal code

6317843764

#### Approval date

2020-06-29, 1399/04/09

#### Ethics committee reference number

IR.AJUMS.REC.1399.304

## Health conditions studied

### 1

#### Description of health condition studied

Duration of the second stage of labor and birth canal injuries

#### ICD-10 code

O94

#### ICD-10 code description

sequelae of complication of pregnancy childbirth and the puerperium

## Primary outcomes

### 1

#### Description

Time of The second stage of labor

#### Timepoint

The second phase of labor

#### Method of measurement

The length of the second stage of labor will be measured through a researcher-made questionnaire.

### 2

#### Description

Episiotomy

#### Timepoint

The fourth stage of labor

#### Method of measurement

recorded through a researcher-made questionnaire during delivery.

### 3

#### Description

Perineal laceration

#### Timepoint

The fourth stage of labor

### Method of measurement

recorded through a researcher-made questionnaire during delivery.

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group 1 (gel): The intervention in the intervention group will be performed during labor after dilation is complete. During the second stage of labor, after wearing sterile gloves by the midwife, gently massage with two index and middle fingers impregnated with lubricant gel purchased from Razak Laboratories in the amount of 5 ml from one wall to another wall of the vagina (in the form of movement and Return (letter U) will be done by gently pushing the rectum up and down so that each part lasts at least a minute. The massage will continue during and between pushing the mother.

##### Category

Treatment - Drugs

#### 2

##### Description

Group 2 Intervention (oil): The intervention in the intervention group will be performed during labor after dilatation is complete. During the second stage of labor, after wearing sterile gloves by a midwife, gently massage with two index and middle fingers dipped in duck tallow oil, from one wall to another wall of the vagina (in the form of a reciprocating motion, the letter U in English) with pressure. Gently move up and down the rectum so that each part lasts at least a minute. The massage will continue during and between pushing the mother. The intervention group will be given a perineal massage with tallow for 5-10 minutes.

##### Category

Treatment - Drugs

#### 3

##### Description

Control group: The control group will receive non-drug massage and routine care during hospitalization.

##### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Shahid Beheshti Hospital in Abadan

###### Full name of responsible person

Mojgan Javad Nouri

### Street address

N0.415/6,Nine Bahar street, Abadan

### City

Ahvaz

### Province

Khouzestan

### Postal code

6315733653

### Phone

+98 61 5332 9401

### Email

Javadnoori-m@ajoms.ac.ir

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Ahvaz University of Medical Sciences

###### Full name of responsible person

Muhammad Bedoui

###### Street address

Golestan

###### City

Ahwaz

###### Province

Khouzestan

###### Postal code

6315733653

###### Phone

+98 61 5332 9401

###### Email

badvi-m@ajums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Ahvaz University of Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

Public

##### Domestic or foreign origin

Domestic

##### Category of foreign source of funding

empty

##### Country of origin

##### Type of organization providing the funding

Academic

### Person responsible for general inquiries

##### Contact

###### Name of organization / entity

Ahvaz University of Medical Sciences

###### Full name of responsible person

Mona Matori Abdollahi

###### Position

Master student

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

dr.Mojgan Javadnoori

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mona Matori Abdollahi

**Position**

Master student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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**Email**

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available