

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Muhammad Bedoui

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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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Latest degree

Bachelor

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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