

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effect of perineal massage with ostrich oil on the rate of episiotomy and perineal laceration in nulliparous women

Protocol summary

Study aim

Determination of the effects of perineal massage with ostrich oil on the episiotomy and perineal laceration in nulliparous women

Design

Randomized clinical trial with two parallel group, blindness, supportive

Settings and conduct

This randomized clinical trial was performed on 80 mothers admitted to the maternity ward of Razi Hospital in Qazvin. We received informed consent from participants. The samples were randomly assigned to intervention (n=40) and control groups (n=40).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Nulliparous women Age 19-35 years old Gestational age from 37 to 42 weeks Singleton and low-risk pregnancy Exclusion criteria: Unreliable embryonic cardiac rhythm History of vaginal surgery

Intervention groups

For the intervention group, Perineal massage with ostrich oil was performed for 5 to 10 minutes in the active phase and 5 to 10 minutes in Second stage of labor. For the control group, the usual care of the delivery room and Ritgen's maneuver were performed in the second stage of labor.

Main outcome variables

Episiotomy, Perineal tear

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190131042567N1**

Registration date: **2019-02-26, 1397/12/07**

Registration timing: **retrospective**

Last update: **2019-02-26, 1397/12/07**

Update count: **0**

Registration date

2019-02-26, 1397/12/07

Registrant information

Name

samira romina

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3336 4517

Email address

s.romina@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-12, 1396/07/20

Expected recruitment end date

2018-07-11, 1397/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of perineal massage with ostrich oil on the rate of episiotomy and perineal laceration in nulliparous women

Public title

Evaluation of the effect of olive oil on perineal laceration

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 19-35 years Nulliparous Gestational age 37-42 week Singleton and low-risk pregnancy

Exclusion criteria:

Unreliable embryonic cardiac rhythm History of vaginal surgery

Age

From **19 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization was used for random assignment. Firstly, the size of 4 blocks was considered. Then based on the sample size, 15 blocks were selected through table of random numbers. Subjects were assigned to the intervention and control groups based on the status of the blocks.

Blinding (investigator's opinion)

Not 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 Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Bahonar Blvd.

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Approval date

2017-10-12, 1396/07/20

Ethics committee reference number

IR.QUMS.REC.1396.306

Health conditions studied**1**

Description of health condition studied

Effect of perineal massage with ostrich oil on the rate of episiotomy and perineal laceration in nulliparous women

ICD-10 code

O70.9

ICD-10 code description

Perineal laceration during delivery, unspecified

Primary outcomes**1****Description**

Episiotomy

Timepoint

After delivery

Method of measurement

Observation

2**Description**

Perineal laceration

Timepoint

After delivery

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: For the intervention group, prenatal massage with ostrich oil for 5-10 minutes in the active phase of labor in the first stage and 5 to 10 minutes in the second stage of delivery will be performed. Massage by a researcher after wearing a sterile gloves and smearing the index finger and mid-engage ostrich oil will move back and forth from the wall to the other side of the vagina, in the form of a U English, and with the pressure to the rectum in the up and down direction.

Category

Other

2**Description**

Control group: The usual care of the delivery room and Ritgen's maneuver were performed in the second stage of labor.

Category

Other

Recruitment centers**1**

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Fatemeh Ranjkesh

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible personDeputy of Research and Technology of Qazvin
University of Medical Sciences**Street address**Qazvin University of Medical Sciences, Bahonar Blvd.,
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apeymani@qums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Qazvin 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**

Qazvin University of Medical Sciences

Full name of responsible person

Fatemeh Ranjkesh

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

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

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

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All the data have code to identify.

When the data will become available and for how long

In 2019

To whom data/document is available

Qazvin University of Medical Sciences

Under which criteria data/document could be used

By confirmation of Qazvin University of Medical Sciences

From where data/document is obtainable

Qazvin University of Medical Sciences

What processes are involved for a request to access data/document

Refer to Qazvin University of Medical Sciences or sending email to franjkesh@qums.ac.ir

Comments