Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 rhytm 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 rhytm 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-engrave 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
Street address
Qazvin University of Medical Sciences, Bahonar Blvd., Qazvin city
City
Qazvin
Province
Qazvin
Postal code
34197-59811
Phone
+98 28 3323 6374
Email
franjkesh@qums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Deputy of Research and Technology of Qazvin University of Medical Sciences
Street address
Qazvin University of Medical Sciences, Bahonar Blvd., Qazvin city
City
Qazvin
Province
Qazvin
Postal code
34197-59811
Phone
+98 28 3333 8034
Email
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
Street address
Qazvin University of Medical Sciences, Bahonar Blvd., Qazvin city
City
Qazvin
Province
Qazvin
Postal code
34197-59811
Phone
+98 28 3333 8034
Email
franjkesh@qums.ac.ir

Person responsible for scientific 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
Street address
Qazvin University of Medical Sciences, Bahonar Blvd., Qazvin city
City
Qazvin
Province
Qazvin
Postal code
34197-59811
Phone
+98 28 3333 8034
Email
Franjkesh@qums.ac.ir

Person responsible for updating data

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
Street address
Qazvin University of Medical Sciences, Bahonar Blvd., Qazvin city
City
Qazvin
Province
Qazvin
Postal code
34197-59811
Phone
+98 28 3333 8034
Fax
+98 28 3323 7268
Email
Franjkesh@qums.ac.ir

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