Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of perineal massage on the rate of episiotomy in primiparous women

Protocol summary

Study aim
Perineal massage Effect on the incidence of episiotomy
Design
in this randomized control trial 100 pregnant women between 18 and 35 years first pregnancy and gestation age between 37 and 42 weeks will enrolled. patients will be accidentally divided into two groups. In intervention group investigator will wear a glove with lubricant and inserting her fingers 2-3 cm into the vagina and compress the vaginal wall for 2 minutes. At least each patient will receive four massage and will rest 30 minutes between massages. control group will receive routine care during labor.
Settings and conduct
This study will be conducted under the supervision of Mashhad university of medical sciences in Omol Banin hospital. Physician who will perform the delivery will unaware of intervention.
Participants/Inclusion and exclusion criteria
pregnant women aged between 18 and 35 with gestational age between 37 and 41 weeks will enrolled the study.
Intervention groups
Investigator will wear a glove with lubricant and inserting her fingers 2-3 cm into the vagina and compress the vaginal wall for 2 minutes.
Main outcome variables
The incidence of episiotomy and laceration will be compered between groups.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20100307003497N2**
Registration date: **2018-04-16, 1397/01/27**
Registration timing: **prospective**
Last update: **2018-04-16, 1397/01/27**
Update count: **0**
Registration date
2018-04-16, 1397/01/27

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
0511-2231444
Email address
akhlaghif@mums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-09-01, 1397/06/10
Expected recruitment end date
2019-03-03, 1397/12/12
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of perineal massage on the rate of episiotomy in primiparous women

Public title
Effect of perineal massage on the rate of episiotomy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
pregnant women between 18 and 35 years first pregnancy gestation age between 37 and 42 weeks first

phase of delivery

Exclusion criteria:

high risk pregnancy underlying disease (HTN, DM, etc)

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

patients will divided based on randomization table into two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Physician who will performed the labor will be unaware about the intervention group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Imam Reza sq , Ebnesina ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

123456

Approval date

2017-09-21, 1396/06/30

Ethics committee reference number

IR.MUMS.fm.REC.1396.186

Health conditions studied

1

Description of health condition studied

delivery

ICD-10 code

O09.219

ICD-10 code description

Supervision of pregnancy with history of pre-term labor, unspecified trimester

Primary outcomes

1

Description

episiotomy and laceration

Timepoint

During labor

Method of measurement

Perineal examination

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group investigator will wear a glove with lubricant and inserting her fingers 2-3 cm into the vagina and compress the vaginal wall for 2 minutes. At least each patient will receive four massage and will rest 30 minutes between massages.

Category

Prevention

2

Description

Control group: control group will receive routine care during labor.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Dr. Farideh Akhlaghi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Mohsen Tafaghodi

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Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Farideh Akhlaghi

Position
Associate professor

Latest degree
Specialist

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Gynecology and Obstetrics

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Person responsible for updating data

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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