Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Assessment of the effect of vaginal and perineal massage with sesame oil compared to gel on labor in primiparous women

Protocol summary

Study aim
Evaluation of the effect of vaginal and perineal massage with sesame oil on labor in primiparous women

Design
A single blind randomized clinical trial with parallel group design, consisted of 180 patients, enrorolled between January 2019 and April 2020.

Settings and conduct
This single blind study will be done at Razi and Sina hospitals in Ahvaz. The samples will be randomly divided into sesame oil, gel and the control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: nulliparous women; fetal age between 37-42 weeks based on ultrasound and LMP; approximate fetal weight between 2500 to 4000 gr; fetal cephalic presentation; maternal age between 18-35 years; written consent to participate in the study. Non-inclusion criteria: chronic maternal disease; high risk pregnancy; body mass index (BMI) > 30.

Intervention groups
Intervention group 1 (Sesame Oil): the vagina and perineum of the participants in this group are massaged by 1 cc of oil for 3 minutes in each vaginal examination in the second stage of labor. Intervention group 2 (gel): the vagina and perineum of participants in this group are massaged by 1cc of gel for 3 minutes in the second stage of labor in each vaginal examination. Control group: the participants in this group receive no intervention in the second stage of labor.

Main outcome variables
Need to episiotomy; perineal laceration; length of second stage of labor

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170422033583N1**
Registration date: **2020-03-21, 1399/01/02**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-21, 1399/01/02**
Update count: **0**

Registration date
2020-03-21, 1399/01/02

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3221 4184

Email address
shushtaripour.f@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-05, 1398/10/15

Expected recruitment end date
2020-04-19, 1399/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessment of the effect of vaginal and perineal massage with sesame oil compared to gel on labor in primiparous women

Public title
The effect of vaginal and perineal massage with sesame oil on labor

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Primiparous women Gastational age between 37 to 42 weeks based on ultrasound and LMP Approximate fetal weight between 2500 and 4000 gr Single live fetus Cephalic presentation Maternal age between 18 to 35 years Written consent to participate in the study
Exclusion criteria:
Chronic illness in the mother Emergency cesarean section following fetal distress, placenta abruption, cord prolapse or intrauterine growth retardation Precipitate labor body mass index (BMI) > 30 High risk pregnancy Need to do induction
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization using random numbers table
Blinding (investigator's opinion)
Single blinded
Blinding description
Sesame oil and gel will be prepared in completely similar glasses and the participants will be unaware of the content of glasses.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ahvaz Jundishapur University of Medical Sciences
Street address
No23; before Zand intersection; between Katanbaf and Basangeideh; Shahid Masjedi street
City
Ahvaz
Province
Khouzestan
Postal code
6195774589
Approval date
2019-12-28, 1398/10/07
Ethics committee reference number
IR.AJUMS.REC.1398.693

Health conditions studied

1

Description of health condition studied
Reduce episiotomy and perineal laceration
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Reduce the length of the second stage of labor
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Need for episiotomy
Timepoint
After the intervention
Method of measurement
partograph chart and labor progress record

2

Description
Perinael laceration
Timepoint
After the intervention
Method of measurement
partograph chart and labor progress record

3

Description
Length of second stage of labor
Timepoint
After the intervention
Method of measurement
partograph chart and labor progress record

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1 (Sesame Oil): the vagina and perineum of the participants in this group are massaged

by 1 cc of Sesame oil for 3 minutes in each vaginal examination in the second stage of labor.

Category

Prevention

2

Description

Intervention group 2 (gel): the vagina and perineum of participants in this group are massaged by 1cc of gel for 3 minutes in each vaginal examination, in the second stage of labor.

Category

Prevention

3

Description

Control group: the participants in this group receive no intervention in the second stage of labor.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Mojgan Javadnoori

Street address

Phelestine street; Amanyeh

City

Ahvaz

Province

Khouzestan

Postal code

6195774589

Phone

+98 61 3333 3050

Email

fatshush@gmail.com

2

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Mojgan Javadnoori

Street address

Gandomkar 5 street; Imam Ali square; Kootabdolah

City

Ahvaz

Province

Khouzestan

Postal code

6195774589

Phone

+98 61 3555 0592

Email

fatshush@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Muhammad Badavi

Street address

Golestan highway

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3373 8333

Email

fatshush@gmail.com

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

Mojgan Javadnori

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Second Floor; Ahvaz School of Nursing and Midwifery; Shahre Daneshgahi; Golestan Road

City

Ahvaz

Province

Khouzestan

Postal code
6135715794
Phone
0098613367543
Email
javadnoori-m@ajums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mojgan Javadnoori
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
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Khouzestan
Postal code
6135715794
Phone
0098613367543
Email
javadnoori-m@ajums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mojgan Javadnoori
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
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Email
javadnoori-m@ajums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Title and more details about the data/document
Total data is Shared after making people unidentifiable.
When the data will become available and for how long
Start the access period: 6 months after printing the results.
To whom data/document is available
Researchers working in college or industry-base companies can take data of this study.
Under which criteria data/document could be used
Researchers working incollege or industry -based companies can use the results after getting permission from the authors of the study.
From where data/document is obtainable
Second Floor; Ahvaz School of Nursing and Midwifery; Shahre Daneshgahi; Golestan Road, IRAN.P.BOX:6135715794. E-mail:javadnoori-m@ajums.ac.ir
What processes are involved for a request to access data/document
Two weeks after receiving the request
Comments