

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 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, enrolled 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 Gestational 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

Perineal 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
Second Floor; Ahvaz School of Nursing and Midwifery;
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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
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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 in college 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