

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of massage with ginger oil on waist circumference in reducing the pain tension at active phase of labor in primigravida

Protocol summary

Study aim

Effect of massaging the waist region with ginger oil on the severity of pain in the active phase of labor in primipara women

Design

Clinical trial with two groups of intervention and one control group, with parallel, double-blind, randomized groups

Settings and conduct

With the onset of uterine contractions in dilates 4-5, 6-7, and 8-10 cm with deep breathing, The participant is placed in a sitting position or sitting, and the massage is carried out continuously during contraction for 15 minutes without contraction. For the intervention group massage the area of the waist with an appleberry with ginger oil or Paraffin oil is done. The start of intervention in the active phase and the dilatation will be 4 to 5 centimeters. Pain Questionnaire (VAS) is completed by the researcher before and immediately after the completion of each massage procedure for the intervention group (groups 1 and 2). The pain control questionnaire (VAS) of the control group will be filled out at each stage of the mentioned dilatations once a day. Place of the study: Um Al-Benin Maternity Hospital affiliated to Mashhad University of Medical Sciences

Participants/Inclusion and exclusion criteria

Satisfaction with entering the study- Iranian and resident of Mashhad- parturition prime- Single pregnancy and live

Intervention groups

Two groups of intervention (1: Gingerbread Gum Massage - 2: 1): Paraffin Paralysis (inactive) and a control group (routine nursing care during the active phase of labor) are carried out.

Main outcome variables

Determination of intensity of active phase of labor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180513039643N1**
Registration date: **2018-08-02, 1397/05/11**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-02, 1397/05/11**

Update count: **0**

Registration date

2018-08-02, 1397/05/11

Registrant information

Name

Marzyeh Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3868 3630

Email address

maryazizi1395@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-01, 1397/05/10

Expected recruitment end date

2018-11-01, 1397/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of massage with ginger oil on waist circumference in reducing the pain tension at active phase of labor in primigravida

Public title

Effect ginger oil on reducing pain labor

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Satisfaction with entering the study Iranian and resident of Mashhad parturition prime Single pregnancy and live The age of the mother is 35- 18 No history of eczema and allergy to medicinal herbs No exclusion of massage A healthy water bag or less than 12 hours of water rupture Cephalic presentation

Exclusion criteria:

twin pregnancy Alcohol and Drug Addiction Company dissatisfaction with the study

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked Block: The blocking method will be performed in such a way that: Given that this research is a triple group, then the groups will be initially named A, B, and C. Then, create 6 blocks (ABC -ACB-BCA-BAC-CAB-CBA) and draw lots to arrange these × blocks to determine which blocks are first, second, and which six will be. Then, with the arrival of each patient, it will be clear which group should be included.

Blinding (investigator's opinion)

Double blinded

Blinding description

The same packing and oil coding will be done by the pharmacist.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Ethics committee of Mashhad University of

Medical Sciences

Street address

Mashhad University Street, Quraishi Building

City

Mashhad

Province

Razavi Khorasan

Postal code

91735951

Approval date

2018-07-11, 1397/04/20

Ethics committee reference number

IR.MUMS.REC.1397.094

Health conditions studied**1****Description of health condition studied**

Labor pain

ICD-10 code

XV

ICD-10 code description

Pregnancy, childbirth and the puerperium

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

Severity of pain in the active phase of labor in primipara women

Timepoint

The time intervals of pain measurement with the Visual Analogue Scale are performed before and immediately after each massage at each group (group 1 and 2), and in the control group, in the dilatation, 4-5 /6-7 /8-10

Method of measurement

Measuring pain intensity with the Visual Analogue Scale

Secondary outcomes

empty

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

Intervention group: The intervention group: the beginning of intervention in the active phase and the dilatation is 4 to 5 centimeters. How to do massage in this way, with the onset of the contraction of the pain in the intervention group, 10 to 15 drops of oil deposited in the closed containers A or B, and its materials for the researcher and the mothers can not be understood. (2% ginger or paraffin oil) in the area, and the mass of the sacral vertebra ends in the upstream to the lumbar vertebrae. Ginger extract will be prepared from the company and will then be delivered to the laboratory with base oil at a concentration of 2%.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Women of Umm Al Binhayn Hospital

Full name of responsible person

Ms. Dr. Mir Tameori

Street address

Crossroad of Zarrine, Ayatollah Behjat 16

City

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9114734706

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oah.it@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

صدیقه یوسف زاده

Street address

University of Mashhad, Faculty of Nursing and Midwifery

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9913197319

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Email

YousefzadehS@mums.ac.ir

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

marzyeh azizi

Position

Senior midwifery student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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maryazizi1395@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Marzyeh azizi

Position

MSc Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

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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