Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Mashhad

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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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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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Person responsible for scientific inquiries

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Name of organization / entity
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Position
MSc Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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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