Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Survey Effectiveness of Back Massage on Process of Pain and Delivery Labor Outcomes in Primiparous Women

Protocol summary

Study aim

Comparison of the effect of back massage on the duration of the first stage of labor in both case and control groups Comparison of the effect of back massage on the duration of the second stage of labor in both case and control groups Comparison of the effect of back massage on the duration of the third stage of labor in both case and control groups.

Design

In this study, 60 pregnant mothers who are nulliparous and eligible for admission to the Alavi Center are selected. Participants are randomly divided into two intervention and control groups and each participant is given a dedicated code.

Settings and conduct

The Type of Study will be a Clinical Trial with Two Groups of Massage and Control. The Statistical Population of Pregnant Women is at the Threshold of Delivery in Ardabil City. In this Clinical Trial Study,60 Subjects (30 Massage and 30 Controls) Were Selected from Women Referring to Ardabil Alavi Hospital with Continuous Sampling And Random Sampling. In The Massage Group, 4 Centimeters of Cervical Dilatation Will Result in Three Massage Therapies Until Delivery. control group will receive routin care.

Participants/Inclusion and exclusion criteria

The criteria for entering the study included normal pregnancy, singleton,cephalic presentation , dilatation above 4 cm, have criteria for massage, lack of participation in the physiological delivery class, exclusion criteria including mother's unwilling to continue massage, lack of massage therapy criteria

Intervention groups

The study participants will include pregnant women in the active phase of labor that will be referred to the Alavi hospital in Ardabil. Mothers will receive three half-hour massage times if they have the entry criteria and after obtaining the consent of the company in the study in dilatation 5-7 -9 cm.

Main outcome variables

Pain Intensity; Duration of Pain

General information

Reason for update

Acronym

تأثیر ماساژ

IRCT registration information

IRCT registration number: **IRCT20140118016255N5**
Registration date: **2019-01-15, 1397/10/25**
Registration timing: **retrospective**

Last update: **2019-01-15, 1397/10/25**
Update count: **0**

Registration date

2019-01-15, 1397/10/25

Registrant information

Name

Roya Nikjou

Name of organization / entity

Ardabil University of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-14, 1396/11/25

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Survey Effectiveness of Back Massage on Process of Pain and Delivery Labor Outcomes in Primiparous Women

Public title
Effect of Back Massage on Process of Pain and Delivery Labor Outcomes
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Normal and Term pregnancy Singleton Cephalic presentation 4 cm dilatation Have Massage criteria Lack of Participation in the Physiological Delivery Class
Exclusion criteria:
Mother's Withdrawal from Continue Massage Have any illness
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple Randomization, Block
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants Will be Unaware of the Allocation of Intervention type in Two Groups
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ardabil University of Medical Sciences
Street address
End of the University of Ardabil University of Medical Sciences
City
Ardabil
Province
Ardabil
Postal code
۵۶۱۸۹-۸۵۹۹۱
Approval date
2018-01-22, 1396/11/02
Ethics committee reference number
IR.ARUMS..1396.204

Health conditions studied

1

Description of health condition studied
Labor Pain
ICD-10 code
O80-O84
ICD-10 code description
O80-O84

Primary outcomes

1

Description
Severity of Pain
Timepoint
Dilation 5-7-9 cm
Method of measurement
Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: The study participants will include pregnant women in the active phase of labor that will be referred to the Alavi hospital in Ardabil. Mothers will receive three half-hour massage times if they have the entry criteria and after obtaining the consent of the company in the study in dilatation 5-7 -9 cm. Control Group: In control group will receive routin care.
Category
Prevention

2

Description
Control group: In the control group, participants will receive routine care.
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Alavi hospital

Full name of responsible person
Roya Nikjou

Street address
Hafez Square, Faculty Of Nursing And Midwifery

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Ardabil 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

2

Sponsor

Name of organization / entity
Ardabil University of Medical Sciences

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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
Ardabil 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
Ardabil University of Medical Sciences

Full name of responsible person
Roya Nikjou

Position
Lectur

Latest degree
Master

Other areas of specialty/work
Midwifery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
data held in common after anonymous
When the data will become available and for how long
unlimited
To whom data/document is available
popular
Under which criteria data/document could be used
no condition
From where data/document is obtainable
researcher
What processes are involved for a request to access data/document
6 month
Comments