

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 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 routine 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)

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+98 45 1771 7137

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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

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Sponsors / Funding sources

1

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

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

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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