

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the efficacy of Massage therapy and Breathing Techniques on Pain, physiologic responses to the labor Pain and delivery's process and out comes among Mothers admitted to Alzahra hospital in Tabriz

Protocol summary

Summary

The objective of this Cross over randomized, one blind trial is to investigate the effect of Massage therapy and Breathing Techniques on Pain intensity, physiologic responses to the labor Pain (Ph R) and labor process & out comes and compare them among Mothers. The 40 primigravidas who have inclusion criteria were chosen and were divided randomly into two groups of massage1(M1) and Breathing1(B1). Then 42 other mothers were chosen with the same condition and were divided into two groups: massage 2(M2) and Breathing 2(B2) randomly. . Educated researcher assistant (ERA) gave practical education to (B1,2) by holding one class on that day. By beginning the labor, the (ERA) went to the labor room, done Massage and assisted mothers for Breathing of in 4, 6, 8 and 10 centimeter of dilatation for 30 minutes. We did not use any intervention on control groups at the same dilatations. The intensity of pain was measured by NRS (Numerical rating scale) 30 minutes after appointment of dilatation and the physiologic responses were evaluated at the same times. Process of labor was evaluated by partograph. The difference of means analyzed by T- test, Wilcoxon signed-rank test, data of labor process & out comes analyzed by using chi-square. of labor process & out comes analyzed by using chi-square.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109136582N2**
Registration date: **2012-03-13, 1390/12/23**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-13, 1390/12/23

Registrant information

Name

Mahin Kamalifard

Name of organization / entity

Tabriz University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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+98 414796770

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Recruitment status

Recruitment complete

Funding source

Tabriz university of medical sciences

Expected recruitment start date

2011-04-03, 1390/01/14

Expected recruitment end date

2014-04-20, 1393/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of Massage therapy and Breathing Techniques on Pain, physiologic responses to the labor Pain and delivery's process and out comes among Mothers admitted to Alzahra hospital in Tabriz

Public title

Comparison of the efficacy of Massage therapy and Breathing Techniques on Pain, physiologic responses to the labor Pain and delivery's process and out comes in Tabriz

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion: -primigravidas who expected to have normal childbirth and have 20-35 years old, single fetus with 36≤gestational age and without any physical disease(such as kinds of paralyse) that can affect the research exclusion: -the sampels asking for pharmacologic methods of pain relief - adminstration of oxytosin or other drugs

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **82**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz university of medical scienses

Street address

University of Medical Sciences and Health Services,Daneshgah street

City

Tabriz

Postal code

Approval date

2006-08-13, 1385/05/22

Ethics committee reference number

85611

Health conditions studied

1

Description of health condition studied

labor pain-Pelvic and perineal pain

ICD-10 code

O24-O25-R1

ICD-10 code description

Categories O24.- and O25 include the listed conditions even if they occur during childbirth or the puerperium.

Primary outcomes

1

Description

labor Pain intensity

Timepoint

first & second stage of labor

Method of measurement

NRS (Numerical rating scale)

2

Description

physiologic responses to the labor Pain (pals rate, blood pressure &body temperature)

Timepoint

first & second stage of labor

Method of measurement

Pals rate counting for one minute,one blood pressure instrument,termometr

Secondary outcomes

1

Description

labor process

Timepoint

first & second stage of labor

Method of measurement

partogram

2

Description

kind of labor

Timepoint

end of first & second stages of labor

Method of measurement

observation & writting it

3

Description

infants APGAR

Timepoint

first & fifth minute after birth

Method of measurement

standard table of APGAR score

Intervention groups

1

Description

cervical Dilatation4&8cm Breathing 1 , Massage1
INTERVENTION

Category

Other

2

Description

The causes of dividing Breathing & massage groups to (B1,2),(M1,2) was that each group has control group in all dilatations therefore the B1 samples did breathing techniques in 4,8 dilatations (case) and the samples of B2 group did not use breathing techniques in that dilatations and became control group. The B2 samples did breathing techniques in 6,10 dilatations (case) and the samples of B1 group did not use breathing techniques in that dilatations and became control group. The M1 samples take massage in 4,8 dilatations (case) and the samples of M2 group did not take massage in that dilatations and became control group. The M2 samples take massage in 6,10 dilatation (case) and the samples of M1 group did not take massage in that dilatations and became control group.

Category

Treatment - Other

3

Description

Cervical dilatation 6 & 10 cm Breathing1and Massage1
are control

Category

Other

4

Description

Cervical dilatation 4 & 8 cm Breathing2 and Massage2
are control

Category

Other

5

Description

Cervical dilatation 6 & 10 cm, intervention, Breathing2,
Massage2

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Doctor Manigeh Sayahmelli

Street address

Bagshomal Crossroad, Southern Artesh St.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz university of medical sciences-research
principal

Full name of responsible person

research service

Street address

Tabriz university of medical sciences-research
principal

City

Tabriz

Grant name

Grant code / Reference number

85611

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz university of medical sciences-research principal

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

nursung &midwifery faculty

Full name of responsible person

Mahin Kamalifard

Position

master of scienses/lecturer-academic member

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, shariaty street

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Tabriz

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5138947977

Phone

+98 41 1479 6770

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+98 41 1479 6969

Email

kamalifardm@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty