Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the efficacy of Massage therapy and Breathing Techniques on Pain, physiologic responses to the labor Pain and delivery’s processand out coms amoung Mothers admitied to Alzahra hospital in Tabriz

Protocol summary

Summary

The objective of this Cross over randomized,one blind trial is to investigate the effect Massage therapy and Breathing Techniques on Pain intensity, physiologic responses to the labor Pain (Ph R) and labor process & out comes and comparison them among Mothers”.The 4o 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 to 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 Breathingof in 4, 6, 8 and 10 centimeter of dilatation for 30 minuets.We dident use any intervention on control groups at the same dilatations. The intensity of pain was measured by NRS (Numerical rating scale) 30 minuets 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)

Phone

+98 414796770

Email address

kamalifardm@gmail.com

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 processand out coms amoung Mothers admitied 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 coms 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 Scienses 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
024-025-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
City
Tabriz
Postal code

5138947977

Phone

+98 41 1479 6770

Fax

+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