

# 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 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)

###### 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 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

##### City

Tabriz

##### Postal code

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**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*