

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### The effect of heat and cold therapy on labor pain and outcomes in nuliparous women

#### Protocol summary

##### Summary

This study is a randomized control trial for determining the effect of hot and cold therapy on labor pain and child birth outcomes in nuliparous women. One hundred twenty eight low risk parturient women are randomly divided to four groups: heat, cold, intermittent heat and cold and control groups. Inclusion criteria are: null parity, 18 to 35 years old, early active phase (3-4 cm dilatation), cephalic presentation, 37-41 weeks of gestation, and singleton pregnancy. Exclusion criteria are: CPD, history of chronic pelvic pain, IUFD, fetal distress, use of narcotic or sedative drugs, psychological disorders and skin diseases in intervention area. Pain severity is assessed in 3-4cm, 6-7 cm, 9-10 cm dilatations of cervix and second stage of delivery by VAS. Duration of first, second and third stage of labor, first and fifth minutes APGAR, FHR, delivery kind, perineum status and mother satisfaction are assessed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201108277422N1**

Registration date: **2012-05-20, 1391/02/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-05-20, 1391/02/31

##### Registrant information

###### Name

Zhila Ganji

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Recruitment status

**Recruitment complete**

###### Funding source

Research chancellor of mazandaran university of medical sciences

###### Expected recruitment start date

2011-09-06, 1390/06/15

###### Expected recruitment end date

2012-05-04, 1391/02/15

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

The effect of heat and cold therapy on labor pain and outcomes in nuliparous women

###### Public title

The effect of heat and cold therapy on labor pain and outcomes

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

inclusion criteria consisted of women in the age range between 18-35 years-women was active labor (3-4 cm dilatation) - Cephalic presentation - gestational age between 37-41 weeks - being a singleton fetus -Exclusion criteria included disproportion between fetus and pelvic-a history of chronic pelvic pain - prolapsed cord - fetal death, abnormal fetal heart patterns, narcotic use, mental disorders and skin diseases are the interference region Randomization \*

**Age**

From **18 years** old to **35 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **128**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Chancellor of Mazandaran University of  
Medical Sciences

**Street address**

Moalem square

**City**

Sari

**Postal code**

481615793

**Approval date**

2011-09-04, 1390/06/13

**Ethics committee reference number**

H-89-26

**Health conditions studied****1****Description of health condition studied**

Labor

**ICD-10 code**

O80

**ICD-10 code description**

spontaneous vertex delivery

**Primary outcomes****1****Description**

severity of pain

**Timepoint**

first and second stage labor

**Method of measurement**

visual analog scale

**Secondary outcomes****1****Description**

duration of labor

**Timepoint**

first and second stage

**Method of measurement**

digital clock

**2****Description**

SATISFACTION OF LABOR

**Timepoint**

After labor

**Method of measurement**

questionnaire

**Intervention groups****1****Description**

1-In The heat therapy group warm water bag will be used for low back and abdominal area from cervix dilatation of 3-4 cm to the end of first labor during contractions and for perineum at the second stage .

**Category**

Other

**2****Description**

2-in the cold therapy group ice water bag will be used for low back and abdomen from cervix dilatation of 3-4 cm to the end of first labor during contractions and for perineum at the second stage .

**Category**

Other

**3****Description**

3- IN the intermittent heat and cold therapy group warm water and ice water bag will be used intermittently for low back and abdomen from cervix dilatation of 3-4 cm to the end of first stage of labor during contractions and for perineum at the second stage .

**Category**

Other

**4****Description**

4-control grope will br recived rotin care. a midwife will be with woman all time.

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shahid Rajaei Hospital

**Full name of responsible person**

Zhila Ganji

**Street address**

Tonakabon

**City**

Tonakabon

**2**

**Recruitment center**

**Name of recruitment center**

Ilimam Ali Amol Hospital

**Full name of responsible person**

Zhila Ganji

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**City**

Amol

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Research Chancellor of Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr. Ahmadali Enayati

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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**

Research Chancellor of Mazandaran University of Medical Sciences

**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**

**Name of organization / entity**

Nasibah Nursing and Midwifery School

**Full name of responsible person**

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**Position**

MSc

**Other areas of specialty/work**

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**Postal code****Phone**

00

**Fax****Email****Web page address****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*