

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

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Iran (Islamic Republic of)

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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

queztionaier

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 perinea 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 perinea 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 perinea 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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Chamestan Road

City

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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

Zhila Ganji

Position

MSc

Other areas of specialty/work

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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