Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the effect of two methods of heat therapy and cold therapy on labor pain and delivery outcome in primigravida women referred to the Karaj hospital in 2014

Protocol summary

Summary

The aim of this study is to determine the effect of two methods of heat therapy and cold therapy on labor pain and delivery outcome in primiparous women. This study is a randomized , single blind and multi-center with three groups. The study populations include primiparous women with singleton term pregnancies with cephalic presentation and without any medical problems or pregnancy complications. They don't use any drug or method of analgesia and anesthesia and labor induction. The sample include 105 patients (three groups of 35 persons) will be randomly allocated into the following three group: experimental group (heat therapy, cold therapy) and control group (routine care). Intervention in heat group is use of heat bag put in the low back (at least 60 min inthe first stage of labor) and in the second stage put on perineum (at least 4 min).Intervention in cold group is similar but ice bag put that area for 10 min. For the control group will be done routine management. Assessment of pain in the first stage of labor will be done in 3-4cm cervical dilatation,6-7 cm and 9-10cm in three groups according to the McGill Pain index. Duration of the first, second and third stages of labor, type of delivery and neonatal Apgar score at 1 and 5 minutes after birth, perineal laceration and fetal heart tone in the first stage of labor, in three groups will be recorded

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407115948N2**
Registration date: **2014-08-07, 1393/05/16**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-08-07, 1393/05/16

Registrant information

Name

Soheila Moghimi Hanjani

Name of organization / entity

Islamic Azad University Karaj Branch

Country

Iran (Islamic Republic of)

Phone

+98 21 7720 4224

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Islamic Azad University of Karaj

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of two methods of heat therapy and cold therapy on labor pain and delivery outcome in primigravida women referred to the Karaj hospital in 2014

Public title

Effect of heat therapy and cold therapy on delivery

outcome

Purpose

Supportive

Inclusion/Exclusion criteria

Iinclusion criteria:female18-35,pregnant women in active phase of labor,cephalic persentation,primipara with 37-41week gestational age,singleton pregnancy
Exclusion criteria: cephalo pelvic disproportion,history of choronic pelvic pain, Use of any drug or method of analgesia and anesthesia, induction of labor with Oxytocin,complication of labor(cord prolaps,placenta abraptio,abnormal position),history of infertility, abnormal fetal heart patterns, presence of any special medical condition (e.g. chronic diseases) and use of narcotic drugs .

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad university Karj barnch

Street address

Crossroad of Moazen Blvd and Esteghlal Blvd, Rajaeeshahr, Karaj, Mailbox: 31485-313

City

Karaj

Postal code

31485-313

Approval date

2014-03-12, 1392/12/21

Ethics committee reference number

0064

Health conditions studied

1

Description of health condition studied

Out comes of delivery

ICD-10 code

z-37

ICD-10 code description

Delivery

Primary outcomes

1

Description

Labor pain intensity

Timepoint

Dilation 3-4,6-7,9-10 cm

Method of measurement

McGill pain questionnaire

2

Description

Duration of the first stage of labor

Timepoint

One time the start of labor until complete effacement and cervical dilatation

Method of measurement

According to minutes using the standard digital clock

3

Description

Duration of the second stage of labor

Timepoint

One time from full dilatation of cervix to departure of baby

Method of measurement

According to minutes using the standard digital clock

4

Description

Duration of the third stage of labor

Timepoint

One time from departure of baby to complete withdrawal of placenta

Method of measurement

According to minutes using the standard digital clock

5

Description

Type of delivery

Timepoint

One time after departure of baby

Method of measurement

Observed as a vaginal delivery, instrumental delivery and cesarean section

6

Description
Apgar score
Timepoint
At 1 and 5 minutes after birth
Method of measurement
Observation and examination

Secondary outcomes

1

Description
Fetal heart tone
Timepoint
Every half of time
Method of measurement
Sounic aid and digital clock

2

Description
perineal laceration
Timepoint
after delivery
Method of measurement
observation and examination

Intervention groups

1

Description
In heat therapy group:in the first stage ,heat bag put in the low back(at least 1 hours) and the second stage put in perineum for 4 minutes
Category
Other

2

Description
In cold therapy group:ice bag put in the low back for 10 minutes in the first stage and on perineum in the second stage
Category
Other

3

Description
In control group:routin management
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Alborz hospital
Full name of responsible person
Soheila Moghimi Hanjani
Street address
Alborz hospital, Parastar Blvd, Western Baghestan, Mianjadeh
City
Karaj

2

Recruitment center
Name of recruitment center
Bahonar hospital
Full name of responsible person
Zahra Meddizadeh Toorzani
Street address
Specialized Bahonar hospital, Azimieh three-way
City
Karaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Islamic Azad University of Karaj branch
Full name of responsible person
Ahmad Jahan Latibary
Street address
Vice chancellor for research, Islamic Azad University of Karaj branch, Crossroad of Moazen Blvd and Esteghlal Blvd, Rajaeeshahr
City
Karaj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Islamic Azad University of Karaj branch
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
Islamic Azad University Karaj branch

Full name of responsible person
Soheila Moghimi Hanjani
Position
Master of midwifery
Other areas of specialty/work
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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