

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 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

soheila.moghimi@kiau.ac.ir

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

Inclusion criteria: female 18-35, pregnant women in active phase of labor, cephalic presentation, primipara with 37-41 week gestational age, singleton pregnancy

Exclusion criteria: cephalo pelvic disproportion, history of chronic pelvic pain, Use of any drug or method of analgesia and anesthesia, induction of labor with Oxytocin, complication of labor (cord prolapse, placenta abruption, 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**Street address**Crossroad of Moazen Blvd and Esteghlal Blvd,
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Full name of responsible person

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

Zahra Mehdizadeh Toorzani

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z_mehdizadeh_t@yahoo.com

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*