Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the effect of heat and cold therapy on outcomes of labor and satisfaction in primigravida women referred to the Kamali hospital in Alborz 2015

Protocol summary

Summary

This randomized control trial, single-blind, with control group and single-center study is designed for exterminating and comparing the effect of heat and cold therapy on outcomes of labor and satisfaction in primigravida women.One hundred twenty low risk parturient women are randomly divided to three groups: heat therapy, cold therapy and control groups. The main inclusion criteria consisted of nulliparous women, 18 to 35 years old, early active phase (3-4 cm dilatation), cephalic presentation, 37-41 weeks of gestation, and singleton pregnancy. exclusion criteria include pre diagnosed of psychological and anatomical disorders, indications for cesarean section, history of chronic pelvic pain, use of narcotics and sedative and skin diseases in intervention area. Intervention will apply in the form of heat and cold therapy in the first and second stages of labor. Outcome variables include pain severity in first stage (3-4, 5-6, 7-8 and 9-10cm dilatation) and second stage of labor with the McGill Pain linear scale, duration of the first, second and third stages of labor, fetal heart rate in the first stage, mode of delivery, Apgar score, the first lactation, hugging the baby after delivery and variables of maternal satisfaction. Finally the items listed in each of the three groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015031021020N1**
Registration date: **2015-03-10, 1393/12/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-03-10, 1393/12/19

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Research Chancellor of Alborz University of Medical Sciences

Expected recruitment start date

2015-03-06, 1393/12/15

Expected recruitment end date

2015-08-22, 1394/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of heat and cold therapy on outcomes of labor and satisfaction in primigravida women referred to the Kamali hospital in Alborz 2015

Public title

Compared the effect of heat and cold therapy on outcomes of labor

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria consisted of nulliparous women in the age range between 18-35 years, women in the active phase of labor (3-4 cm dilatation), cephalic presentation, gestational age between 37-41 weeks and being a singleton fetus without preset abnormalities. Exclusion criteria included pre diagnosed of psychological and anatomical disorders, pre diagnosed of chronic diseases, indications for cesarean section, abnormal fetal heart patterns, history of chronic pelvic pain, history of infertility in women or spouse, any problem created during labor, women's unwillingness to continue to heat or cold therapy, women who live apart from their spouses, use of narcotics in about 8 hours before of active labor and skin diseases, including any injury, inflammation and eczema in the region of using hot-cold therapy.

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: **120**

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

Research Chancellor of Alborz University of Medical Sciences

Street address

Ninth Floor, Dara Building, North Yasaman, East Pune Avenue, 45 meter of Golshahr

City

Karaj

Postal code

Approval date

2015-02-02, 1393/11/13

Ethics committee reference number

2519365

Health conditions studied

1

Description of health condition studied

normal vaginal delivery

ICD-10 code

O80

ICD-10 code description

spontaneous vertex delivery

Primary outcomes

1

Description

Severity of pain

Timepoint

First and second stage of labor

Method of measurement

McGill Pain linear scale

2

Description

Duration of stages of labor

Timepoint

First, second and third stages of labor

Method of measurement

Digital clock

Secondary outcomes

1

Description

Mother's satisfaction

Timepoint

Postpartum

Method of measurement

Questionnaire

Intervention groups

1

Description

In the first intervention group: In The heat therapy group will be used warm water bag during contraction in the first stage of labor for at least 60 minutes on the lower back, abdomen area and under abdomen and in second stage will be used warm water bag for at least 4 minutes on the perineum.

Category

Other

2

Description

In the second intervention group: In The cold therapy group will be used cold ice bag on the lower back, abdomen and under abdomen for 10 minutes once every

30 minutes during the first stage and and in second stage will be used cold ice bag on the perineum for 5 minutes every 15 minutes.

Category

Other

3

Description

In the control group: This group will be recived routine care of labor ward and a midwife will be with woman all the time.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali Hospital

Full name of responsible person

Zahra Mehdizadeh Tourzani

Street address

Kamali Hospital, Kamali Street, Shohada Square, Shahid Beheshti Avenue

City

Karaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Chancellor of Alborz University of Medical Sciences

Full name of responsible person

Dr. Enayatollah Kalantar

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Ninth Floor, Dara Building, North Yasaman, East Pune Avenue, 45 meter of Golshahr

City

Karaj

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Chancellor of Alborz 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

Alborz University of Medical Sciences

Full name of responsible person

Zahra Mehdizadeh Tourzani

Position

Master of Midwifery/ Faculty member

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