

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Oct 2026

Comparison of the effect of infrared belt with hot water bag on pain intensity and duration of first stage of labor in primipara women

Protocol summary

Study aim

Comparison of the effect of infrared belt with hot water bag on pain intensity and duration of first stage of labor in primiparous women

Design

Clinical trial with control group, parallel groups, randomized without blinding

Settings and conduct

The study site is Mashhad Hospital, Mashhad. Sampling is easy. In both groups, the intervention was performed in two cycles for 20 minutes, in the lumbar region of mothers in the first stage of labor, in 4-5 cm dilation and then in 6-7 cm dilation. The duration of the contractions, the severity of the contractions, are recorded and recorded every 10 minutes every half hour. The mean score of pain intensity in the intervention groups was measured by the researcher in the first stage of labor, immediately after the uterine contraction, before the first intervention cycle, and immediately after the two intervention cycles, and at the end of the first phase of labor, ie, 10 cm dilation of the cervix. . .

Participants/Inclusion and exclusion criteria

Inclusion criteria: be Iranian. • The age of delivery is 18-35 years. • Be literate. • be primiparous. • singleton is. • Show fetal head peak. • Exclusion criteria: • Have drug and alcohol addiction and tobacco. Mother discontinued from continuing research. Emergency caesarean section is indicated for any reason. • Affected by medical conditions

Intervention groups

This study included two intervention groups (infrared belt and hot water bag) and one control group.

Main outcome variables

Severity of labor pain, duration of first stage of labor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190805044446N1**

Registration date: **2019-12-03, 1398/09/12**

Registration timing: **retrospective**

Last update: **2019-12-03, 1398/09/12**

Update count: **0**

Registration date

2019-12-03, 1398/09/12

Registrant information

Name

fateme dastjerd

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4263 5925

Email address

dastjerd941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-27, 1398/05/05

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of infrared belt with hot water bag on pain intensity and duration of first stage of labor in primipara women

Public title

The effect of heat therapy on pain intensity and duration of labor

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Be Iranian. • The age of delivery is 18-35 years. • Be literate. • Sign a written consent form. • be primiparous. • Be monotonous. • Show fetal head peak. • The fetal head fits the mother's pelvis. Gestational age is 38 weeks to 42 weeks based on the first day of the last menstrual period or ultrasound of the first trimester of pregnancy. Estimated weight of the fetus using Johnson's law or ultrasound after 32 weeks will be between 25,000 to 4,000 grams. Spontaneous labor has begun (4-5 cm dilatation with at least two contractions of 20 or 30 seconds and more within 10 minutes). • The intensity of labor pain should be greater than 3 on the visual pain scale (10 cm ruler). Do not have speech-auditory or dialect problems that impede communication with the researcher. • Do not have drug and alcohol and tobacco addiction. • Has not had a psychiatric or psychologist experience, medication or hospitalization due to mental illness during the past year. • Has not been under major stress for the past 6 months. • Not be affected by medical conditions. • Do not have midwifery problems. • Has no history of surgery on the uterus or cervix. • Have not used the medicine prescribed by your doctor, midwife or herbal medication for the past 24 hours to start labor pain. • The mother's oral temperature should not be equal to or greater than 38 ° C. • Do not have severe anxiety. • Do not have scars, scratches, burns, eczema or lumbar lesions that prevent heat treatment.

Exclusion criteria:

Mother to discontinue continuing research. Emergency caesarean section is indicated for any reason. Use oxytocin to induce labor or accelerate labor. Use narcotics, Entonox, numbness. • There are signs of fetal distress. • Observe any abnormal cases, such as hypertonic contractions or rapid tibial systolic dysfunction and disturbances in the vital signs of the mother and others • Observe any possible side effects of the infrared belt (skin burns, increased maternal body temperature, abnormal fetal heart sound, abnormal uterine contractions, maternal intolerance to the infrared belt or hot water bag) • Mother's intolerance of infrared belt or hot water bag • Other cases

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: **162**

Randomization (investigator's opinion)

Randomized

Randomization description

Block of six, which is done by computer.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

This is a three-group study

Secondary Ids

empty

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

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad School of Nursing and Midwifery, doktora squar, Mashhad .

City

Mashhad

Province

Razavi Khorasan

Postal code

1062807413

Approval date

2019-07-13, 1398/04/22

Ethics committee reference number

IR.MUMS.NURSE.REC.1398.029

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

Birth pain

ICD-10 code

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ICD-10 code description

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

Severity of pain with shortened McGill questionnaire

Timepoint

At the beginning of the study, after the first intervention, after the second intervention, at the end of the first phase

Method of measurement

shortened McGill questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Infrared Belt: Two cycles of 20 minutes intervention by infrared belt in first stage of labor for 40 minutes total

Category

Treatment - Devices

2

Description

Intervention group 2: Hot water bag,two cycles of 20 minutes intervention by hot water bag in first stage of labor for 40 minutes total

Category

Treatment - Devices

3

Description

Control group: Third group Control group: Routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Om albanin hospital

Full name of responsible person

fateme erfania

Street address

Mashhad School of Nursing and Midwifery

City

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Razavi Khorasan

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Phone

+98 51 5118 5756

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erfaniaf@mums.ac.ir

Web page address

<https://www.um.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

erfania fateme

Street address

Doctoral crossroads

City

mashhad

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Web page address

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Grant name

Evidence-Based Care Research Center

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

erfania fateme

Position

science Committee

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

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Web page address
<https://www.um.ac.ir/>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Information about the main outcome is shared

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Unable to access data

From where data/document is obtainable

Dastjerd941@mums.ac.ir

What processes are involved for a request to access data/document

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Comments

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