Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effects of red and near-infrared light diode radiation with acupressure on pain intensity and length of the first stage of labor in primiparous women

Protocol summary

Study aim
Comparison of the effect of red and near-infrared LED radiation with acupressure on pain intensity and length of the first stage of labor in primiparous women.

Design
A phase 2, randomized, two-group, unblinded clinical trial using convenient sampling will be conducted in Umm al-Banin (S) and Hasheminejad hospitals in Mashhad on 90 primiparous pregnant women. Randomization was performed using the website sealedenvelope.com.

Settings and conduct
This research will be carried out at Umm al-Banin Hospital in Mashhad. People are randomly divided into LED light and acupressure groups. Interventions in Hugo and Sanyingiao acupressure points will be performed in dilations 4-5, 7-6, and 9-8. Interventions will be in the form of light radiation with wavelengths of 660 and 850 in the amount of 3 joules of energy per LED for 10 minutes in the light radiation group and pressing the above points for 10 minutes for each point in the acupressure group.

Participants/Inclusion and exclusion criteria
Primiparous pregnant women with the following criteria: active labor, cephalic presentation, term fetus, singleton and weighing 2.5 to 4 kg, absence of medical disease, and obstetric complications will be included in the study. In case of any obstetric complications such as bleeding and fetal heart rate disorders, the pregnant mother will not be included in the study.

Intervention groups
The main intervention group: pregnant mothers who will receive LED light radiation in the Hugo and Saninjiao points in addition to the routine care of childbirth in the three stages of dilatation. Control group: The control group includes pregnant mothers who, in addition to receiving routine care during childbirth, such as maternal vital signs, fetal heart rate check, and acupressure at Hugo and Sanyingiao points.

Main outcome variables
Intensity of labor pain, duration of first stage of labor

General information

Reason for update
The estimated date for sampling differed from the exact sampling time and needed to be corrected.

Acronym

IRCT registration information
IRCT registration number: **IRCT20230725058918N1**
Registration date: **2023-08-30, 1402/06/08**
Registration timing: **prospective**

Last update: **2025-06-22, 1404/04/01**
Update count: **1**

Registration date
2023-08-30, 1402/06/08

Registrant information

Name
Fahime Nouri
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-23, 1402/05/01

Expected recruitment end date
2024-02-19, 1402/11/30

Actual recruitment start date
2023-11-22, 1402/09/01
Actual recruitment end date
2024-03-05, 1402/12/15
Trial completion date
2024-03-05, 1402/12/15

Scientific title
Comparing the effects of red and near-infrared light diode radiation with acupressure on pain intensity and length of the first stage of labor in primiparous women

Public title
The effect of red and infrared LED light on labor pain and length
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A pregnant mother aged 18-35 must be primiparous, single, and Iranian. Have a fetus with cephalic presentation with a gestational age of 37-41 (based on LMP or ultrasound of the first trimester of pregnancy). Having literacy in reading and writing and the absence of speech and hearing problems that prevent communication with the interventionist. Signed the written consent form. The estimated weight of the fetus (based on Johnson criteria or third trimester ultrasound) should be between 2.5-4 kilos. Cerebral-pelvic disproportion and fetal anomaly have not been diagnosed. The onset of labor should be spontaneous based on 4 cm dilation and regular uterine contractions. Absence of drug and alcohol addiction, as well as not having used narcotics for 8 hours before the intervention. Do not have medical diseases. Do not have obstetric complications. Do not have a history of surgery on the uterus or cervix. Do not have lesions such as wounds, scratches, burns, eczema, or other lesions on the skin that prevent light therapy.
Exclusion criteria:
In case of any obstetric complications such as bleeding and fetal heart rate disorders, the pregnant mother will not be included in the study.
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: **90**
Actual sample size reached: **81**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling method in this research will be easy based on entry and exit criteria. Allocation of people to two groups will be random and based on the sequence generated by the site https://www.sealedenvelope.com, blocks of four without replacement. Allocation of code A or B to each of the groups will be based on lottery. To hide the allocation, the closed envelope method is used in such a way that a number of envelopes, preparation, and each of the randomly created sequences are recorded on a card and the cards are placed inside the envelopes in order. At the time of selecting the research units, based on the order of entry into the study, the envelopes are opened and the assigned group of that participant is revealed.
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
Ethics Committee of Mashhad University of Medical Sciences
Street address
Nursing and Midwifery School , Shahid Dr. Kharazmi Educational Building, University Campus, East Gate of Ferdowsi University of Mashhad, Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9177949025
Approval date
2023-07-26, 1402/05/04
Ethics committee reference number
IR.MUMS.NURSE.REC.1402.064

Health conditions studied

1

Description of health condition studied
Labor pain intensity and length of the first stage of labor
ICD-10 code
O80.0
ICD-10 code description
Spontaneous vertex delivery, Prolonged first stage (of labor)

Primary outcomes

1

Description

Pain intensity of labor

Timepoint

Measurement of pain score and pain intensity upon entering the study, then after intervention in cervical dilatations of 4-5, 7-6 and 8-9 cm

Method of measurement

Pain score and intensity will be measured through the visual analog pain scale tool and McGill short pain questionnaire.

2

Description

Length of first stage of labor

Timepoint

The length of the first stage of labor will be measured by the universal partograph form.

Method of measurement

The length of the first stage of labor will be calculated from the time the pregnant mother enters the active phase (at the time of entering the study) until the dilatation of 10 cm of the cervix.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Irradiation of LED light in each of Hugo and Suningyao acupressure points for 10 minutes in dilations 4-5, 7-6 and 9-8

Category

Treatment - Devices

2

Description

Intervention group: Squeezing Hugo and Suningyao points for 10 minutes for each point in 4-5, 6-7, and 8-9 dilatations.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Umm al-Binin Hospital, Mashhad

Full name of responsible person

Dr. Masoume Mirtimori

Street address

16 Behjat, Ayatollah Behjat St., Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

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

Fahime Nouri

Position

Master student of midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Assistant Professor of Reproductive Health

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Person responsible for updating data

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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