Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

Compare effects of cold and heat therapy on labor pain intensity and duration of labor in nulliparous women who referred to Iran haspital

Protocol summary

Study aim

Determination effects of cold and heat therapy on labor pain intensity and duration of labor in nulliparous women who referred to Iran haspital

Design

105 women were recruited allocated to the cold therapy.heat therapy and the control group.A comparative experimental design was used to achieve the objecyives of the study.In order to select the research units the samples were placed one day in cold therapy,heat therapy and control group respectively. Inclusion criteria were samples who willingly participated or excluded from the study.vaginal examination which assessed based on dilation of the cervix. if they met a dilation of less than 4 cm criteria,they ere recruite as heat and cold therapy or control group.In the study there is not rendomization and blinding.

Settings and conduct

This study is done in Iran Iran-Shahr Hospital. The sample size was 105 patients in three groups: Cold Therapy, heatTherapy and Control.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: Age: 18 to 35 years; At the beginning of the active phase of labor (dilation of 3 to 4CM); Gestational age: 37 to 41 weeks; Single pregnancy pregnancy ;Cephalopods Exit criteria: . Gestational hypertension; Poly and Oligo-Hydramonus with ultrasound ; Reducing fetal movements; IUGR; Fetal death; Any complications experienced during the study; unwillingness to continue the intervention

Intervention groups

Heat and cold therapy were applied as interventions in this study. the heat therapy group received warm water bags over low back and suprapubic area while in the cold therapy group ice bag applied ti woman"s low back and perineal area. no intervention was conducted in the control group. Intensity of labor pain compared in the three groups.

Main outcome variables

The effect of intervention on the severity of labor pain and the length of delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180624040219N1**
Registration date: **2018-09-19, 1397/06/28**
Registration timing: **prospective**

Last update: **2018-09-19, 1397/06/28**
Update count: **0**

Registration date

2018-09-19, 1397/06/28

Registrant information

Name

Mahnaz Didevar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3722 6579

Email address

mahnaz.didevar@irshums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Compare effects of cold and heat therapy on labor pain intensity and duration of labor in nulliparous women who referred to Iran haspital

Public title
The effect of curative and thermotherapy on the severity of labor pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
1- Age 18 to 35 years 2. At the beginning of the active phase of labor (dilatation 3 to 4CM) 3- Gestational age 37- 41 weeks 4- Single-crowned pregnancy 5- Cephalic sedation

Exclusion criteria:
1- Diagnosis of mental and anatomical disorders (psychosis, schizophrenia, uterine anomalies, pelvic stenosis 2. Chronic known disease (heart disease, pulmonary, hypertension, diabetes Skin diseases (any lesion, inflammation and eczema in the area of thermal therapy and cold therapy Gestational hypertension Cephalopods10. Poly and Oligo-Hydramonus with ultrasound Reduce fetal movements12- IUGR13. Fetal death1 Rupture of curtains for more than 12 hours. Discontinuity of the head of the fetus with the pelvis Abnormal heartbeat patterns History of chronic pelvic pain Infertility record Any complications experienced during the study (abnormal placenta, abnormal position of the embryo, umbilical cord prolapse) unwillingness to continue the intervention Use of any medication or analgesia

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)
Not randomized

Randomization description

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 Iranshahr University of Medical Sciences

Street address
Balooch Blvd

City
Iranshahr

Province
Sistan-va-Balouchestan

Postal code
9914786138

Approval date
2017-06-19, 1396/03/29

Ethics committee reference number
iR.IRSHUMS.REC.1396.3

Health conditions studied

1

Description of health condition studied
The effect of Thermal Therapy and Cold Therapy on the severity of labor pain and delivery time

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Initial Outcome Assessment of labor pain according to vas

Timepoint
Before intervention, dilatation of 3 cm, dilatation 5-6 cm, dilatation of 10-9 cm, and second stage of labor

Method of measurement
Visual Analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: In the heat therapy group, the level of heat in the bag is controlled by the forearm of the researcher's hands,the heat bag cover by tine cloth the first stage is placed in the lower back and in the second stage in the supraPubic and Its duration depends on the desire of woman. The acceptable duration for a first-time heat therapy is at least 60 minutes and in the second stage, at least 5 minutes. The temperature of the hot water bottle is adjusted between 38-40. The severity

of pain will be measured in the dilatation 3-4, 7-8, 10-9 and the second stage of delivery with the Visual Analogue Scale (VAS). The duration of the first, second and third stages of labor, the first and fifth minute APGAR, mean heart rate, type of delivery, perineum status and maternal satisfaction will be assessed.

Category

Treatment - Devices

2

Description

Intervention group: Second intervention group: Cold Therapy. Before of any intervention, the severity of the pain in the 4 cm dilatation is measured by showing a graded ruler. the Ice Bag cover by thin cloth and put on back in the first stage and it put in second stage in the perineal and suprapubic . The acceptable duration for cold therapy is at least 60 minutes in the first stage and at least 5 minutes in the second stage. The temperature of the ice bag is between 0 to -5 degrees.The severity of pain will be measured in the dilatation 3-4, 7-8, 10-9 and the second stage of delivery with the Visual Analogue Scale (VAS). The duration of the first, second and third stages of labor, the first and fifth minute APGAR, type of delivery, perineum status and maternal satisfaction will be assessed.

Category

Treatment - Devices

3

Description

Control group: For the control group, the usual care is done.The severity of pain will be measured in the dilatation 3-4, 7-8, 10-9 and the second stage of delivery with the Visual Analogue Scale (VAS). The duration of the first, second and third stages of labor, the first and fifth minute APGAR, type of delivery, perineum status and maternal satisfaction will be assessed.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranshahr University of Medical Sciences, Iranshahr, Iran Hospital

Full name of responsible person

Mahnaz Didehvar

Street address

Shahid Moradi Boulevard, Iran Hospital

City

Iranshahr

Province

Sistan-va-Balouchestan

Postal code

9914786138

Phone

+98 54 3722 6579

Email

mahnaz.didevar@irshums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranshahr University of Medical Sciences

Full name of responsible person

Tahmine Salehian

Street address

balooch Blvd

City

Iranshahr

Province

Sistan-va-Balouchestan

Postal code

9914786138

Phone

+98 54 3721 0485

Email

tahmine.salehian@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iranshahr 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

Iranshahr University of Medical Sciences

Full name of responsible person

Mahnaz Didehvar

Position

Facuty of Iranshahr university of Medical scinces

Latest degree

Master

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Balooch Blvd

City

Iranshahr

Province

Sistan-va-Balouchestan

Postal code
9914786138

Phone
+98 54 3721 0481

Email
didevar.m@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iranshahr University of Medical Sciences

Full name of responsible person
Mahnaz Didehvar

Position
Faculty

Latest degree
Master

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Balooch Boulvar

City
Iranshahr

Province
Sistan-va-Balouchestan

Postal code
9914786138

Phone
+98 54 3721 0481

Email
didevar.m@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Iranshahr University of Medical Sciences

Full name of responsible person
Mahnaz Didehvar

Position
faculty

Latest degree
Master

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Balooch Boulvar

City
Iranshahr

Province
Sistan-va-Balouchestan

Postal code
9914786138

Phone
+98 54 3721 0481

Email
didevar.m@gmail.com

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