Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

The effect of cold therapy on pain severity and labor outcome of Nulliparous Women

Protocol summary

Summary

The objective of this study is to investigate the effect of cold therapy on pain intensity and delivery outcome in primiparous women. Inclusion criteria: Tendency to participate in the study; Singleton pregnancy between 37 and 41 weeks of gestation; Vortex presentation; Age of 18-35 years old and being primiparous. Exclusion criteria :Lack of tendency to participate in the study;Disorder in delivery stages; Manual removal of placenta;Abnormal fetal heart rate patterns that lead to cesarean section. Sample size: 72 people having the inclusion criteria will be selected and randomly divided into two groups. In the experimental group, a frozen gel pack will be used on the upper and lower sides of abdomen, lower side of waist, and perinea. Pain intensity of delivery stages, bleeding, Apgar score, and women's satisfaction will be measured. Studies outcome: Effect of cold therapy on pain intensity and delivery outcome

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015022321200N1**
Registration date: **2015-07-02, 1394/04/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-07-02, 1394/04/11

Registrant information

Name

Roya Dakhilalah

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4254

Email address

dakhilalah@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cold therapy on pain severity and labor outcome of Nulliparous Women

Public title

The effect of cold therapy on pain severity and labor outcome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Tendency to participate in the study; Singleton pregnancy between 37 and 41 weeks of gestation; Vortex presentation; Age of 18-35 years old and being primiparous. Exclusion criteria :Lack of tendency to participate in the study;Disorder in delivery stages; Manual removal of placenta;Abnormal fetal heart rate patterns that lead to cesarean section.

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: **68**
Randomization (investigator's opinion)
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
The ethic committee of Shiraz University of Medical Sciences
Street address
No 60 ,Zand street, Shiraz University of Medical Sciences,Shiraz, Iran
City
Shiraz
Postal code
Approval date
2015-01-07, 1393/10/17
Ethics committee reference number
CT-9370-7280

Health conditions studied

1

Description of health condition studied
Delivery
ICD-10 code
080.0
ICD-10 code description
Supervision of normal first pregnancy

Primary outcomes

1

Description
Pain severity
Timepoint
First,Second and third stage of labor
Method of measurement
Visual analogue scale

Secondary outcomes

1

Description
Duration of labor stages
Timepoint
Since labor addmision to full dilatation(first stage),since full dilatation to child birth(second stage),since child birth to placenta delivery(third stage)
Method of measurement
Per minute

2

Description
Perineal tears
Timepoint
Immediately after delivery.
Method of measurement
According to the standard definition of tearing the skin, perineum, vagina and cervix

3

Description
Childbearing Satisfaction
Timepoint
After delivery
Method of measurement
Mackey 's standard questionnaire

4

Description
Measurement of hemoglobin
Timepoint
Before and six hours after delivery
Method of measurement
Blood test

5

Description
Neonatal apgar score
Timepoint
First and fifth minutes after delivery
Method of measurement
Apgar score table

Intervention groups

1

Description
Intervention group:Cold therapy(freezed gel pack) on the fundus of the uterus, back and lower abdomen every 30 minutes for 10 minutes and every 10 minutes on perineum for 5 minutes.

Category
N/A

2

Description
control groupe: No intervention will be done
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Zeinab Hospital
Full name of responsible person
Street address
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Shiraz University of Medical Sciences
Full name of responsible person
Dr Basir Hashemi
Street address
No 60 ,Zand Street, Shiraz University of Medical Sciences,Shiraz,Iran
City
Shiraz
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 of Shiraz 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
School of Nursing and Midwifery, Shiraz
Full name of responsible person
Sara Azima
Position
Master's degree in Midwifery, Faculty member
Other areas of specialty/work
Street address
Namazi Sq.
City
Shiraz
Postal code
Phone
+98 71 3647 4254
Fax
Email
azimas@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
School of Nursing and Midwifery, Shiraz
Full name of responsible person
Sara Azima
Position
Master's degree in Midwifery, Faculty member
Other areas of specialty/work
Street address
Namazi Sq.
City
Shiraz
Postal code
Phone
+98 71 3647 4254
Fax
Email
azimas@sums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Department of midwifery ,School of Nursing and Midwifery,Shiraz University of Medical Scientes, Shir
Full name of responsible person
Sara Azima
Position
Master's degree in Midwifery, Faculty member
Other areas of specialty/work
Street address
İNo 73,School of Nursing and Midwifery,Nemazee squair, Shiraz, Iran
City
Shiraz
Postal code
7193613119
Phone
+98 36474254
Fax
+98 36474252

Email
azimas@sums.ac.ir
Web page address
www.sums.ac.ir

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