Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of hot and cold massage on sph6 spot (SP6) on pain reduction in active phase of labor

Protocol summary

Study aim
Determination and Compare the Effect Of Hot And Cold Massages On Point Six Spleen Reducing Labor Pain

Design
Double-blind clinical trial, purpose-based and accessible, with parallel groups and a sample size of 40 people per group

Settings and conduct
This research will be carried out at the Maternity Hospital of Amiralmomenin Hospital in Zabol city. In order to determine the severity of pain before intervention in dilatation of 5-3 cm, after 2 times of uterine contraction and pain expression, the mother is asked to determine the pain score on the pain reliever. . To determine the SP6 point, people are asked to place their 4 fingers next to the ankle and the researcher points to the correct SP6 point. Couples' days with hot massage and the days of intervention with Massagh.

Participants/Inclusion and exclusion criteria
Physical and mental health; dilatation of 4-5cm; literacy in terms of number comprehension; single pregnancy; cephalic presentation and gestational age 38-40 week. Exit conditions include preeclampsia, induction of childbirth; opioid use in the last 8 hours ; Lack of progress; maternal hip disorder ; maternal underlying disease; any lesions in the area under the massage.

Intervention groups
Hot and cold massage group. In the ice group, ice molds will be used in diameter of 2 cm. For hot massage from hot water bag with temperature of 38 to 40 ° C.

Main outcome variables
Labor pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180513039632N2**
Registration date: **2018-06-15, 1397/03/25**
Registration timing: **retrospective**

Last update: **2018-06-15, 1397/03/25**
Update count: **0**

Registration date
2018-06-15, 1397/03/25

Registrant information

Name
Sanaz Nehbandani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 54 3222 8046

Email address
snehbandani2013@zbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-21, 1396/09/30

Expected recruitment end date
2018-05-21, 1397/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of hot and cold massage on sph6 spot (SP6) on pain reduction in active phase of labor

Public title
The effect of SP6 SPOT massage on labor pain

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Physical and mental health Cervical dilation 4-5 cm Literacy in the comprehension of numbers Single and Precursor Pregnancy Cephalic presentation Gestational age 38-40 week
Exclusion criteria:
Preeclampsia Induction of childbirth Drug use within the last 8 hours Lack of delivery Pelvic disproportion of the fetus mother Mother's underlying illness There is any lesion in the massage site
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **80**
Actual sample size reached: **80**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Intervention is done by the researcher in two groups, and an assessment of the severity of pain will be done by a person who is unaware of how to do the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zabol University of Medical Sciences
Street address
No8. Taleghani street
City
Zabol
Province
Sistan-va-Balouchestan
Postal code
9861784678
Approval date
2017-07-11, 1396/04/20
Ethics committee reference number
Zbmu.1.REC.1396.117

Health conditions studied

1

Description of health condition studied
labor pain
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Labor pain
Timepoint
The pain test will be measured 5 minutes after the intervention, 30 minutes after massage and 30 minutes after the intervention.
Method of measurement
McGill Pulse Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: In the ice massage group, 2 cm diameter ice molds will be used. The ice mold will be placed in a nylon bag. The dosage will be rotated in 30 minutes, so that, starting with the intervention, no restraint is given for 1 minute massage and 1 minute, so that the total amount of massage time to 30 minutes.
Category
Other

2

Description
The second intervention group will be used for hot massage from the hot water bottle at a temperature of 38 to 40 ° C. The dosage will be rotated in 30 minutes so that massage begins at the beginning of the intervention, regardless of contractions. Rest 1 minute, so that the total duration of the massage reaches 30 minutes.
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Zabol Amiralmomenin Hospital

Full name of responsible person
SanazNehbandani

Street address
Street Taleghani,Taleghani 47,Zabol

City
Zabol

Province
Sistan-va-Balouchestan

Postal code
9861784678

Phone
+98 54 3222 8046

Email
snehbandani2013@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zabol University of Medical Sciences

Full name of responsible person
Kadije Rezaie keikhaie

Street address
Ferdowsi 3,Ferdowsi Street, Zabol Nursing and Midwifery Faculty,

City
Zabol

Province
Sistan-va-Balouchestan

Postal code
9861734184

Phone
+98 54 3223 0765

Email
snehbandani2013@zbmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Zabol 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
Zabol University of Medical Sciences

Full name of responsible person
Sanaz Nehbandani

Position
Consultant

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
No 8,Taleghani 47

City
Zabol

Province
Sistan-va-Balouchestan

Postal code
9861784678

Phone
+98 54 3222 8046

Fax

Email
snehbandani2013@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zabol University of Medical Sciences

Full name of responsible person
Sanaz Nehbandani

Position
Consultant

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
No 8,Taleghani 47

City
Zabol

Province
Sistan-va-Balouchestan

Postal code
9861784678

Phone
+98 54 3222 8046

Fax

Email
snehbandani2013@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Zabol University of Medical Sciences

Full name of responsible person
Sanaz Nehbandani

Position
Consultant
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Midwifery
Street address
No 8,Taleghani 47
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Sistan-va-Balouchestan
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Fax
Email
snehbandani2013@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
The data of this research will be published in the form of the article.
When the data will become available and for how long
2018
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
For scientific studies
From where data/document is obtainable
Sanaz Nehbandani2013@zbmu.ac.ir
What processes are involved for a request to access data/document
After discussion in the Council is able to send data.
Comments