

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

snebandani2013@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

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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,

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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

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

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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