Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of acupressure and topical magnesium sulfate on the improvement of cervical edema in women during labor

Protocol summary

Study aim
Comparison of the effect of acupressure and topical magnesium sulfate on cervical edema during labor

Design
Clinical trial with control group with parallel groups, double-blind, randomized, phase 2 on 66 pregnant women.

Settings and conduct
This study will be performed in the maternity ward of Mobini Hospital in Sabzevar. Research units are selected by simple sampling, then randomly will be divided to 3 groups of acupressure, topical magnesium sulfate and control group (routine care).The assistant researcher and the participants are unaware of the type of intervention and the study is double-blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 18-35 years old age; full-term pregnancy; singleton pregnancy; multiparous woman; live and healthy fetus; cervical edema in the active phase of labor; low-risk pregnancy Exclusion criteria: Contraindications for vaginal delivery; obstetric and delivery complications

Intervention groups
This double-blind clinical trial study will be performed on 66 pregnant women in 3 groups of acupressure, magnesium sulfate and control group. In the magnesium sulfate group; 10 cc of 50% magnesium sulfate will be poured topically on the cervix. In the acupressure group, pressure will be applied at point SP6 for 30 minutes. Also, the control group will receive routine care.

Main outcome variables
Improve cervical edema

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161222031519N3**
Registration date: **2020-10-21, 1399/07/30**
Registration timing: **prospective**

Last update: **2020-10-21, 1399/07/30**
Update count: **0**

Registration date
2020-10-21, 1399/07/30

Registrant information

Name
Zahra Zare

Name of organization / entity
Sabzevar University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 51 4401 8301

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zarez@medsab.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01

Expected recruitment end date
2021-04-19, 1400/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of acupressure and topical magnesium sulfate on the improvement of cervical edema in women during labor

Public title

Comparison of the effect of acupressure and topical magnesium sulfate on cervical edema during labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Term pregnancy (37-42 weeks) Singleton pregnancy multipar woman The fetus is alive and well Pregnancy is low risk There are not contraindications for vaginal delivery Be in the active phase of labor

Exclusion criteria:

Vaginal bleeding during labor Non-reassuring fetal heart rate Detection of Cephalopelvic disproportion during labor Non-cooperation of pregnant woman

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, "A, B, C" Words are written on 3 pieces of paper and put inside the envelope. Research units are asked to take a piece of paper. Randomization is done for the first three participants, so the process will be repeated for other subjects. A represents the acupressure group, B represents the magnesium sulfate group and C represents the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

For research blinding, drug and acupressure will be conducted by researcher. Examinations for survey cervical edema will be performed by research assistant, who is unaware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Tohidshahr Blvd, Pardis Building, Sabzevar University of Medical Sciences, School of Nursing

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Approval date

2020-10-14, 1399/07/23

Ethics committee reference number

IR.MEDSAB.REC.1399.109

Health conditions studied

1

Description of health condition studied

cervical edema

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Evaluation of cervical edema in vaginal examination

Timepoint

One and two hours after the start of the intervention

Method of measurement

vaginal examination

Secondary outcomes

1

Description

Duration of labor

Timepoint

At the time of delivery

Method of measurement

Timer

Intervention groups

1

Description

First intervention group: In the magnesium sulfate group, 10 cc of 50% magnesium sulfate is poured topically on the cervix through a syringe. The mother is asked not to get out of bed until half an hour after sulfate administration.

Category

Treatment - Drugs

2

Description
Second intervention group: In the acupressure group, pressure is applied at point SP6 for one minute and rested for one minute.The pressure continues with the appropriate force (whitening of half of the nail color) and to the extent that the excitatory reaction of pain, heat, tingling, throbbing and heaviness occurs in the research unit.The intervention is performed each time for one foot. The total intervention time lasts 30 minutes.

Category
Treatment - Other

3

Description
Control group: The control group will receive routine care.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Sabzevar Mobini Hospital

Full name of responsible person
zahra zare

Street address
Kashefi St, Mobini Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sabzevar University of Medical Sciences

Full name of responsible person
Dr Freshteh Ghorat

Street address
Tohidshahr Blvd, Vice Chancellor for Research, Sabzevar University of Medical Sciences

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vc.Research@medsab.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences

Full name of responsible person
zahra zare

Position
Instructor of the midwifery group

Latest degree
Master

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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Position
Instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

It is possible to share all the data while maintaining the principle of not mentioning the names of individuals

When the data will become available and for how long

One year after the publication of the related article

To whom data/document is available

Researchers of university centers

Under which criteria data/document could be used

The data of the present study can be used after obtaining permission and approval from the Vice Chancellor for Research and Technology of Sabzevar University of Medical Sciences

From where data/document is obtainable

Refer to the project manager, zahra zare, with email address: zare1984@yahoo.com. and contact number 051- 44018301

What processes are involved for a request to access data/document

After completing the research and publishing the relevant article, individuals can apply to the Vice Chancellor for Research and Technology of Sabzevar University of Medical Sciences to receive documents and after obtaining permission from this department, send a confirmation from the Vice Chancellor for Research to the project manager Can access documentation.

Comments