Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of acupressure on SP6 point and Rebozo technique on labor pain and experience

Protocol summary

Study aim

Comparison of the average pain score after the intervention during the active phase in the study groups with the control score before the intervention

Design

A single-blind randomized clinical trial, sample size of 90 people including intervention group, acupressure technique, second intervention group, Rebozo technique and third group, control group routine labor care

Settings and conduct

The place of the research is Al-Zahra Educational and Therapeutic Hospital, Taleghani and 29 Bahman, Tabriz and the time of the research is 1402-1403. The necessary information in this research will be completed by the pregnant women and the researcher through questionnaires and checklists.

Participants/Inclusion and exclusion criteria

Inclusion criteria Healthy and singleton pregnant mothers, full-term gestational age, at the beginning of the active phase (4 cm dilatation), cephalic presentation of the fetus, healthy sac of amniotic, existence of a low-risk pregnancy and no medical problems in pregnancy, fetus with an estimated normal weight, no Willingness to receive a painless delivery other than Rebezo and acupressure, not addicted to drugs and smoking Exclusion criteria Mothers with childbirth problems, a history of rapid delivery, a history of chronic systemic, heart, and pulmonary diseases according to the patient's statement and medical record, meconium in the amniotic fluid before the intervention, the presence of any skin disorders and diseases, and bone fractures at the place of acupressure and the Rebozo technique

Intervention groups

One group will be the intervention group, the acupressure technique, the second intervention group will be the Rebozo technique at the beginning of the active phase of labor and the third group will be the control group that will receive routine labor care.

Main outcome variables

labor pain score, labor experience score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110524006582N39**
Registration date: **2024-02-12, 1402/11/23**
Registration timing: **prospective**

Last update: **2024-02-12, 1402/11/23**
Update count: **0**

Registration date

2024-02-12, 1402/11/23

Registrant information

Name

Mahin Kamalifard

Name of organization / entity

Tabriz University of Medical Sciences and Health Services

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-03, 1403/01/15

Expected recruitment end date

2024-08-20, 1403/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of acupressure on SP6 point and Rebozo technique on labor pain and experience

Public title

Comparing the effect of acupressure and Rebozo technique on labor pain and experience

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy nullipar pregnant mothers Gestational age of term At the beginning of the active phase (4 cm dilatation) Cephalic presentation of the fetus Have a healthy amniotic sac The presence of low-risk pregnancy without medical problems in pregnancy, including blood pressure, gestational diabetes, twin and multiple pregnancy, placenta and amniotic fluid disorders, etc. A fetus with an estimated normal weight Reluctance to receive a painless delivery except for Rebezo and acupressure (remifentanil, other pain relief methods such as massage, breathing, etc.) No addiction to drugs and smoking

Exclusion criteria:

Mothers with birth problems including pre-eclampsia, gestational diabetes, cholestasis, discharge and rupture of the amniotic sac, twin and multiple pregnancies, placenta and amniotic fluid disorders, etc. A history of rapid delivery History of chronic systemic, cardiac, pulmonary diseases according to the patient's self-report and medical records Amniotic fluid meconium before intervention The presence of any disorders and skin diseases and bone fractures in the place of acupressure and Rebozo technique

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants were classified by the random block method based on receiving induction or not receiving induction, being nulliparous or multiparous, and the center of the sampling location with block sizes of 3 and 6 and with an allocation ratio of 1:1:1 to three. The group (first group: recipient of acupressure, second group: recipient of Rebozo technique and third group: control group) will be assigned. For Allocation Concealment, the type of intervention will be written on a sheet of paper by a person not involved in the study and placed inside opaque envelopes numbered from 1 to 90. The envelopes will be opened in the order in which the participants entered the study and the type of intervention received will be determined.

Blinding (investigator's opinion)

Single blinded

Blinding description

This research is a single-blind randomized clinical trial. Only the data analyzer,outcom assessor and data safety monitoring border are unaware of the study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committeeof Tabriz University of Medical Sciences

Street address

No2 central building,3rd floor,University street,Tabriz Univerrsity of medical sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2024-01-01, 1402/10/11

Ethics committee reference number

IR.TBZMED.REC.1402.762

Health conditions studied

1

Description of health condition studied

Labor pain and childbirth experience

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

labor pain score

Timepoint

After the contraction at the beginning of the active phase and before the intervention, then it will be measured

every one hour until reaching the second phase and one hour after the end of labor.

Method of measurement

VAS listed line

2

Description

birth experience score

Timepoint

12 to 24 hours after delivery

Method of measurement

Labor Agentry Scale

Secondary outcomes

1

Description

Duration of labor stages

Timepoint

When the dilatation of the cervix reaches 4 cm, it will be recorded in the partograph form.

Method of measurement

Partograph form

2

Description

score of satisfaction with childbirth

Timepoint

12 to 24 hours after delivery

Method of measurement

(Mackey Satisfaction Rating Scale=MCSRS)

3

Description

Apgar score of the baby in the first and fifth minutes

Timepoint

The first and fifth minutes after the birth of the baby

Method of measurement

Baby's Apgar chart

Intervention groups

1

Description

Intervention group: Rebozo recipient group during the active phase (after cervical dilatation reaches 4 cm), while the patient is on his hands and knees or standing, Rebozo is placed around the abdomen or hips, and its ends are in the hands of the midwife (student researcher). - will be seen. Then the researcher will shake the shawl from one side to the other for 20 minutes using small movements. This work will be done with three repetitions in 4-5, 7-8 and 9-10 cm dilatations of the cervix.

Category

Prevention

2

Description

Intervention group: The group receiving acupressure: During the active phase (after cervical dilatation reaches 4 cm), the researcher will apply direct and continuous pressure to the SP6 point with his index finger or thumb, so that when the participant is sitting or lying on the left side, the researcher will press the SP6 point or He will press the Sanyinjiao with his index finger or thumb directly and continuously for one minute. Then 20 to 30 minutes later, pressure will be applied on the opposite leg under the same conditions. This work will be done with three repetitions in 4-5, 7-8 and 9-10 cm dilatations of the cervix.

Category

Prevention

3

Description

Control group: will receive routine labor care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Shaghayegh Aslani

Street address

Army Street, Al-Zahra Hospital

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2

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Full name of responsible person

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Sponsors / Funding sources

1

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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
Tabriz 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

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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
Not applicable

Informed Consent Form
No - There is not 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
No - There is not a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available