Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of Entonex gas with Bl32 and sp6 pressure points on labor pain, labor stages and labor outcomes in primiparous women

Protocol summary

Study aim
Determining the comparison of the effect of Entonex gas with Bl32 and sp6 pressure points on labor pain, labor progress and labor outcomes in primiparous women referred to Taleghani Hospital in Ilam city in 1402

Design
The clinical trial has a control group, antonex and pressure points, with parallel groups, without blinding, block randomization on 90 people, stata software and ralloc package will be used for randomization.

Settings and conduct
This study is a practical plan in the field of natural childbirth by clinical trial method, which will be conducted in Taleghani maternity hospital in Ilam city and will be compared between three groups.

Participants/Inclusion and exclusion criteria
Prime women aged 18 to 35 with a singleton pregnancy Cephalic position of the fetus Not using other anesthesia methods Active phase of labor

Intervention groups
Antonex Group Group of pressure points control group

Main outcome variables
Labor duration, labor pain and maternal and fetal complications after delivery

General information

Reason for update

Acronym
IEPS

IRCT registration information
IRCT registration number: **IRCT20230717058818N1**
Registration date: **2023-08-21, 1402/05/30**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-21, 1402/05/30**
Update count: **0**

Registration date
2023-08-21, 1402/05/30

Registrant information
Name
Shaghayegh Gheitasiilami
Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-11, 1402/05/20

Expected recruitment end date
2024-02-09, 1402/11/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Entonex gas with Bl32 and sp6 pressure points on labor pain, labor stages and labor outcomes in primiparous women

Public title
Comparison of the effect of Entonex gas with Bl32 and sp6 pressure points on labor pain, labor stages and labor outcomes

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to participate in the study Having literacy Singleton pregnancy Gestational age 37 to 41 weeks Fetal cephalic status Women being in the active phase Not suffering from mental disorders No Anatomical disorders Not using other methods of anesthesia Not using oxytocin to induce and strengthen labor

Exclusion criteria:

Multiple pregnancy Mother's chronic illness Skin diseases such as eczema high risk pregnancy

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: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

After receiving written consent, 90 patients will be randomly divided into three groups: Entonex, acupressure, and control, so that there will be 30 people in each group. Balance block randomization method will be used for random and the stata software allocation of people and the ralloc package will be used to create a random sequence. .In this way, 6 blocks with 1 permutation will be created in the following order: 1=ABC 2=ACB 3=CAB 4=CBA 5=BCA 6=BAC Where A represents the Entonex group, B represents the acupressure group and C represents the control group. Then, based on the numbers in the random table, a number will be chosen randomly, and based on the last digit on the right, one of the groups will be used to determine the sequence of randomization. It should be noted that if the number on the right is zero or 7 to 9 when choosing a random number, that number will not be considered and a random number will be selected again. This will continue until all 90 people are assigned to three groups. It should be noted that this method will prevent two groups from being unbalanced, as well as identifying the randomization sequence.

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

Ethics committee of Ilam University of Medical Sciences

Street address

No.5.Resalat Ave,resalat street,Ilam Town

City

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Province

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Postal code

6931956599

Approval date

2023-06-14, 1402/03/24

Ethics committee reference number

IR.MEDILAM.REC.1402.077

Health conditions studied

1

Description of health condition studied

Labor duration, labor pain and maternal and fetal complications after delivery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Labor progress

Timepoint

4 cm dilatation, every one hour during intervention and after delivery

Method of measurement

Checklist of Duration of Labor Stages

2

Description

labor pain

Timepoint

one hour during labor

Method of measurement

Ten Degree Visual Analogue scale

3

Description

Maternal and Neonatal Outcomes

Timepoint

After giving birth and the day after giving birth

Method of measurement

Checklist of Maternal and Neonatal Outcomes

Secondary outcomes

1

Description
Maternal and neonatal complications after delivery
Timepoint
Before birth and one day after delivery
Method of measurement
Checklist of maternal and newborn outcomes designed by the researcher

Intervention groups

1

Description
Intervention group: entonex.Until the client learns how to use the Entonx mask and capsule and identify uterine contractions, the training will continue, and Entonx gas with a mask will be used as self-prescription from the beginning to the end of each uterine contraction.
Category
Rehabilitation

2

Description
Intervention group: point pressures.Acupressure will be performed at BL32 and SP6 points, and pressure will be applied during uterine contractions by two hands of the researcher on both sides. After 30 seconds of pressure, a 30-second rest will be given. In this way, it will continue for 20 minutes, and each time One of these two points is pressed bilaterally, and the instructor will stay with the researcher until the complete training on how to perform acupressure.
Category
Rehabilitation

3

Description
Control group: control.The control group received only routine measures.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani maternity hospital
Full name of responsible person
Dr Sajad Noorollahi
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Dr Sobhan Ghaforian
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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
Ilam 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
Ilam University of Medical Sciences
Full name of responsible person
Shaghayegh Gheitasiilami
Position
Medical intern
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Clinical study report, results are shared

When the data will become available and for how long
Access starts one year after the results are published

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
Analytical studies

From where data/document is obtainable
gheitasi-s@medilam.ac.ir Shaghayegh Gheitasiilami

What processes are involved for a request to access data/document
Information will be sent after the request is reviewed and if the ethical points of the research and the consent of the participants are met.

Comments