

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

The comparison of the effect of Entonox gas and Back massage on Labor pain in Pregnant Women

Protocol summary

Study aim

Comparison of the effect of Entonox gas and back massage on labor pain in pregnant women

Design

A clinical trial with one control group and two intervention groups of Entonox and back massage, with parallel groups, without blinding, randomized by block method, on 84 pregnant women. Random Allocation Software will be used for randomization.

Settings and conduct

Pregnant mothers who refer to Al-Hadi maternity hospital in Shushtar during the study will be included in the study if they are eligible and will be randomly assigned to 2 intervention groups and a control group. This study will be conducted without blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women with term pregnancy and less than 4 births, with regular spontaneous uterine contractions in the active phase of labor. Exclusion criteria: The presence of medical and midwifery problems in the current pregnancy, the presence of contraindications for the use of Entonox and back massage.

Intervention groups

Intervention group 1: In the back massage group, the massage technique will be massage with both hands from the T10 to S4 vertebra in a rhythmic, regular and ascending manner using the deep stroking method and return to the first place by surface stroking method, in 3 times of 15 minutes and during three periods of dilation 4-5, 6-7 and 8-9 cm during contractions. Intervention group 2: In the Entonox group, gas inhalation by the mother in a self-controlled manner, during dilatation of 4 to 10 cm, starts as soon as the abdomen tightens and stops after the end of the pain. Control group: Since no pain reduction method is routinely performed for mothers in the intended maternity hospital, the control group will not receive any intervention, but they will receive psychological support, similar to the other two

groups.

Main outcome variables

labor pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230610058445N1**

Registration date: **2023-08-04, 1402/05/13**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-04, 1402/05/13**

Update count: **0**

Registration date

2023-08-04, 1402/05/13

Registrant information

Name

Zahra Khodarahmi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-09-11, 1402/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The comparison of the effect of Entonox gas and Back massage on Labor pain in Pregnant Women

Public title
The comparison of the effect of Entonox gas and Back massage on Labor pain in Pregnant Women

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Mother's desire to vaginal delivery A single fetus with a view of the apex of the head Gestational age Between 37 to 41 weeks The regularity of the fetal heartbeat with a number of 120-160 beats per minute The mother's vital signs are normal having minimum reading and writing literacy Dilatation 4-5 cm Having at least 2 to 3 spontaneous uterine contractions lasting 40-45 seconds within ten minutes Having less than 4 vaginal deliveries Body mass index 20-30 kg/m² The fit of the fetal head with the mother's pelvis based on clinical examination The estimated weight of the fetus 2500-4000 grams Proportionality of uterine height with gestational age in clinical examination The normality of the number of fetal movements according to the mother's report or the reaction of the result of the non stress test Mother's age between 18-35 years
Exclusion criteria:
The presence of medical and obstetrical problems in the current pregnancy Addiction to tobacco, drugs and alcohol drinks Height less than 145 cm The existence of any obstacles to vaginal delivery Existence of maternal or fetal risk factors The existence of contraindications for back massage (lumbar disc herniation, skin diseases, fever, etc.) The existence of contraindications to the use of Entonox (mother's inability to hold the mask, maxilla and facial fractures, impaired consciousness and intoxication, impaired oxygen supply, upper respiratory tract infection or respiratory disease, nasal deviation, chronic obstructive pulmonary disease, receiving large amounts of intravenous narcotics, vitamin B12 deficiency and mothers treated with vitamin B12, maxillofacial surgery in the last month, inner ear obstruction, fetal distress, unstable hemodynamic status, some heart diseases such as pulmonary hypertension, problematic airway, fullness of the mother's stomach and schizophrenia)

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: **84**

Randomization (investigator's opinion)

Randomized

Randomization description
The sampling method will be accessible and based on the Inclusion criteria. In this way, after obtaining written consent from the samples, people are assigned to groups by block randomization. Entry of people into each of the groups is done according to the number of the selected blocks and the arrangement inside the block. At first, we divide the samples into two categories: primiparous and multiparous, Then, based on the sample size, we evaluate all possible modes of block formation. as regards that the sample size is 84 people and the number of groups is 3, we will have 42 primiparous mothers and 42 multiparous mothers. So we will have 14 blocks of 6, 7 blocks for primiparous and 7 blocks for multiparous. The randomization tool will be the Random Allocation Software.

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 Lorestan University of Medical Sciences
Street address
Lorestan University of Medical Sciences, Shahid Anoushirvan Rezaei Sq, Moalem Ave
City
Khoram abad
Province
Lorestan
Postal code
6813833946

Approval date
2023-05-24, 1402/03/03

Ethics committee reference number
IR.LUMS.REC.1402.096

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

Measurement of pain at the beginning of the study (before the intervention) and in the dilation of 4-5, 6-7 and 8-9 cm during the intervention.

Method of measurement

Visual analog scale (VAS)

Secondary outcomes

1

Description

The rate of changes in the mother's heart rate

Timepoint

Once before the intervention and then at 4-5, 6-7 and 8-9 cm dilation during the intervention.

Method of measurement

Contec pulse oximetry model CMS50D

2

Description

The amount of changes in the mother's blood oxygen saturation percentage

Timepoint

Once before the intervention and then at 4-5, 6-7 and 8-9 cm dilation during the intervention.

Method of measurement

Contec pulse oximetry model CMS50D

Intervention groups

1

Description

Control group: Since no pain reduction method is routinely performed for mothers in the intended maternity hospital, the control group will not receive any intervention, but they will receive psychological support, similar to the other two groups. If the mother requests to receive the pain reduction method, these people will be excluded from the study.

Category

Other

2

Description

"Intervention group 1": In the back massage group, the massage technique will be massage with both hands from the T10 to S4 vertebra in a rhythmic, regular and ascending manner using the deep stroking method (deep pressure on the layers of the skin, muscles, fascia and tissue binder) and return to the first place by surface stroking method (soft pressure on the skin and its surrounding layers), in 3 times of 15 minutes and during

three periods of dilation 4-5, 6-7 and 8-9 cm during contractions. Vaseline will be used to reduce the friction between the hand and the skin of the mother's back during the massage. The position of the mother while receiving the massage will be lying on the left side for all samples.

Category

Other

3

Description

"Intervention group 2": In the Entonox group, gas inhalation by the mother in a self-controlled manner, during dilatation of 4 to 10 cm, starts as soon as the abdomen tightens (about 30 or 40 seconds before the onset of pain) and stops after the end of the pain (the mask is removed). The combination of nitrous oxide gas (N₂O) or laughing gas with equal amounts of oxygen in a chamber is called Entonox. Entonox capsule should be placed in a vertical position and turned several times before use; Because nitrogen oxide is heavier than oxygen and the gases must be mixed well. The mask must be the size of the mother's face and must be firmly attached to the mother's face; also, proper ventilation should be established to prevent the remaining of the released gases in the environment.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Hadi maternity hospital in Shushtar city

Full name of responsible person

Zahra Khodarahmi

Street address

Al-Hadi Hospital, Kamarbandi St., Shahid Rajaei West Crossroads

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

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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

Khoram-Abad 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**

Khoram-Abad University of Medical Sciences

Full name of responsible person

Mozhgan Masoodi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific**inquiries****Contact****Name of organization / entity**

Khoram-Abad University of Medical Sciences

Full name of responsible person

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Position

Associate Professor

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

Ph.D.

Other areas of specialty/work

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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

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