Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A comparative study on the effect of Enonox gas and B massage on the severity of labor pain in primiparous and multiple women.

Protocol summary

Study aim

Determination and comparison of the effect of Entonox gas and B massage on the severity of labor pain

Design

Clinical trial with controlle and intervention group, parallel group with 69 spicements, randomized, double-blind, sampling between October 2015 until February 2017

Settings and conduct

In this research, simple sampling method with random allocation to groups was used. Women who met the criteria for entry into the research requirements and at the time of the study, due to labor pain, they were referred to the hospital and admitted, easily entered the study. In three groups, the severity of pain is measured by the McGill Scale (VAS) before intervention. In the Entonox group, a dilatation of 4 to 5 cm and more, the study unit entered the study and provides explanations and training on how to use Entonox gas and the time it is used.The mother is told to put her hand on her abdomen and as soon as the abdominal stiffness lasts about 30 to 40 seconds before the onset of pain and inhale the gas in a deep and quiet tail. Gas inhalation continued until the end of the pain and after the end of the pain, gas inhalation was stopped. In fact this method is the mother's participation in the course of her treatment and is a kind of self-control and was continued until delivery. In the massage group, a dilatation of 4 to 5 cm and more, the study unit entered the study, when the abdomen was tightened, (it is stated by the mother) the mother was lying lateral or standing so that her hands were leaning forward on the bed and the researcher's help was left behind and on the left or right of the mother. As soon as the abdomen was tightened and declared by the mother, with the palm of the hand, massage started from the lower back of the waist in a transverse direction from one side to the other, moving with the hands moving down and the buttocks, and moving the gap between the two hips and then down and returning to the first.The massage was actually in the form of B, the straight line is the lower back of the waist and the two rings were two hips.The third group, the control group, received routine care.The severity of pain was measured by McGill Scale every 45 minutes to 225 minutes in the first stage of labor and in the second stage of delivery one time until delivery in all three groups. In order to randomize, the cards were prepared and three numbers 1, 2 and 3, were written and placed inside the packets in an unspecified manner and research unit removed one of the envelopes, if there was a number 1 in the group of B massage, number 2 in the group of Entonox gas, number 3 in the group of usual care were placed. Based on the inclusion criteria and obtaining a written consent of the samples about how to do the study, information about pain intensity immediately before intervention and 45, 90, 135,180, 225 minutes after intervention, delivery type, duration of the active phase of the first stage of labor, duration of the second stage of labor, postpartum hemorrhage through the examination and observation were collected. In order to blind the study the assessor from the group assigned to the samples was not aware.The researcher did not know from the group assigned to the specimens.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women aged between 18-35 years old, Women with first, second, third and fourth pregnancies, Gestational age between 37 and 41 weeks, Singletone pregnancy, Head of presentation(cephalic), Women in dilatation 4-6 centimeter or more; Non-compliance criteria: High-risk pregnant women (presence of previous scars on the uterus and abdomen, diabetic women, preeclampsia and eclampsia, Polyhydramnious, Oligohydramnious, fetal death and etc.) There are skin or lumbar problems in the lower back region in the massage group

Intervention groups

Entonox gas group, B massage group

Main outcome variables

Severity of the active phase pain in the first and second stage of labor, type of delivery, postpartum hemorrhage,

neonatal Apgar score, need for newborn resuscitation

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180128038535N2**
Registration date: **2018-02-25, 1396/12/06**
Registration timing: **retrospective**

Last update: **2018-02-25, 1396/12/06**
Update count: **0**
Registration date
2018-02-25, 1396/12/06

Registrant information
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Mehri Rezaie
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2015-10-23, 1394/08/01
Expected recruitment end date
2016-12-21, 1395/10/01
Actual recruitment start date
2015-10-23, 1394/08/01
Actual recruitment end date
2017-02-19, 1395/12/01
Trial completion date
empty

Scientific title
A comparative study on the effect of Enonox gas and B massage on the severity of labor pain in primiparous and multiple women.

Public title
Determination of the effect of Entonox gas and B massage on the severity of labor pain
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women aged between 18-35 years old Women with first, second, third and fourth pregnancies Gestational age between 37 to 41 weeks Singletone pregnancy Head of presentation(cephalic) Women in dilatation 4-5 centimeter or more
Exclusion criteria:
High-risk pregnant women (presence of previous scars on the uterus and abdomen, diabetic women, preeclampsia and eclampsia, Polyhydramnious, Oligohydramnious, fetal death and etc.) There are skin or lumbar problems in the lower back region in the massage group
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **69**
Actual sample size reached: **69**
Randomization (investigator's opinion)
Randomized
Randomization description
In this research, simple sampling method with random allocation to groups was used.Women who met the criteria for entry into the research requirements and at the time of the study, due to labor pain, they were referred to the hospital and admitted, easily entered the study. For random assignment, among those who entered the study according to the criteria for entering the study, based on the randomasation, they fell into one of the groups B massage, Entonox gas and usual care (the cards were prepared and three numbers 1, 2 and 3, were written and placed inside the packets in an unspecified manner and research unit removed one of the envelopes, if there was a number 1 in the group of B massage, number 2 in the group of Entonox gas, number 3 in the group of usual care were placed.).
Blinding (investigator's opinion)
Double blinded
Blinding description
Clinical care (interventionist)was unaware of the goals of the study and researcher did not know from the group assigned to the specimens.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Saveh University of Medical Sciences
Street address
Headquarters building., Islamic Republic Ave

City
Saveh
Province
Markazi
Postal code
3919676651
Approval date
2015-07-26, 1394/05/04
Ethics committee reference number
IR.SAVEHUMS.REC.139401

Health conditions studied

1

Description of health condition studied
Entonox gas: Entonox is a mixture of two gases of oxygen and nitrous oxide (N2O) and is prescribed to a pregnant woman via a mask.When she feels pain during contraction of uterus in the stages of labor, put a special mask on her face and from inside it takes a deep breath.The gas enter the lungs and then the brain and affects pain centers that reduce feelings of pain.
ICD-10 code
ICD-10 code description

2

Description of health condition studied
B massage: One of the types of massage. Massage of the bottom of the back and is in the form of B. During uterine contractions, the masseur is in a standing or kneeling position next to the mother and carries out massage.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Severity of pain in the active phase of the first stage and second stage of labor
Timepoint
Immediately before the intervention, 45, 90, 135, 180 and 225 minutes after intervention
Method of measurement
Visual analogue Scale of McGill Pain

2

Description
Type of delivery
Timepoint
After intervention
Method of measurement
Observation

Secondary outcomes

1

Description
Postpartum hemorrhage
Timepoint
After intervention in the third stage of labor
Method of measurement
Observation and estimation of bleeding based on the need for hemoglobin to be checked in the first 6 hours after delivery, blood transfusion, need for uterine massage or prescribe misoprostol

2

Description
Apgar score of the infant in the first and fifth minutes of birth
Timepoint
After intervention and delivery
Method of measurement
Neonate Apgar Scale

3

Description
The need for newborn resuscitation
Timepoint
After intervention and delivery
Method of measurement
Neonatal resuscitation according to national protocol

Intervention groups

1

Description
Intervention group: Entonox gas group
Category
Treatment - Other

2

Description
Intervention group: B massage group
Category
Treatment - Other

3

Description
Control group: The usual care group
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahrivar 17th hospital
Full name of responsible person
Mehri Rezaie

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3915644146
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mehrangize_rezai@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Saveh University of Medical Sciences
Full name of responsible person
Hamid Reza Baradaran
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Grant name
Academic development research
Grant code / Reference number
180500300
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Saveh 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
Saveh University of Medical Sciences
Full name of responsible person
Mehri Rezaie
Position
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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