Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Evaluation of the effectiveness of self-hypnosis in pain relief during labor in pregnant women

Protocol summary

Study aim
There are various methods to reduce labor pain; one of the most intense forms of pain. Natural methods could diminish usage of different types of analgesic methods during delivery and provide mother calmness. Hypnosis is a noninvasive method that could decline pain, fear, and anxiety. Therefore we aimed to evaluate the effectiveness of hypnosis on normal vaginal delivery (NVD) pain.

Design
A controlled non-randomized, non-blinded, clinical trial with a parallel group on 45 patients

Settings and conduct
All pregnant women with good hypnotizability and were candidate for first NVD between September 2018 and May 2020 were trained hypnosis. In delivery room, these inductions were applied by a trained midwife on pregnant mothers without using any medicine, anesthetic or analgesic methods. Pregnant mothers who received 25-50 milligrams intravenous Pethidine during delivery in this time period were considered as intravenous analgesic group. Also pregnant mothers who used neither analgesic nor anesthetic method were recruited as physiologic group. All deliveries were done in Mashhad, Bentolhoda Hospital with equivalent care.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Pregnant women are candidates for the first NVD Exclusion criteria: Pregnant women with pregnancy related diseases

Intervention groups
Hypnosis group: Pregnant women who were trained delivery pleasing inductions and pain control conditioning since 32th week of pregnancy, in three 30-minute sessions at intervals of 3 weeks. In delivery room, these inductions were applied by a trained midwife on pregnant mothers without using any other analgesic methods. Physiologic group: Pregnant mothers who received neither analgesic nor anesthetic drugs for delivery. Intravenous analgesic group: Pregnant mothers who received Pethidine during delivery.

Main outcome variables
Labor pain, anxiety, depression, fear

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200802048271N1**
Registration date: **2020-10-02, 1399/07/11**
Registration timing: **retrospective**

Last update: **2020-10-02, 1399/07/11**
Update count: **0**

Registration date
2020-10-02, 1399/07/11

Registrant information

Name
Zahra Valipour

Name of organization / entity

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Iran (Islamic Republic of)

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+98 51 3882 1691

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-23, 1397/06/01

Expected recruitment end date
2020-06-20, 1399/03/31

Actual recruitment start date
2018-08-23, 1397/06/01

Actual recruitment end date

2020-06-20, 1399/03/31

Trial completion date

2020-06-20, 1399/03/31

Scientific title

Evaluation of the effectiveness of self-hypnosis in pain relief during labor in pregnant women

Public title

Effect of hypnosis in pain relief during childbirth in pregnant women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women who are candidate for the first vaginal delivery Pregnant women who had good hypnotic induction profile

Exclusion criteria:

History of gestational diabetes History of intrauterine growth restriction (IUGR) History of any comorbidities in current pregnancy History of previous vaginal delivery Use of neuraxial blocking agents during delivery

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Medical faculty of Mashhad University of Medical Sciences

Street address

Imam Reza Hospital, Imam Reza Sq., Ibn-e Sina Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Approval date

2019-01-22, 1397/11/02

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.775

Health conditions studied

1

Description of health condition studied

Normal vaginal delivery

ICD-10 code

O80

ICD-10 code description

Encounter for full-term uncomplicated delivery

Primary outcomes

1

Description

Labor pain

Timepoint

Immediately after delivery

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

State and trait anxiety

Timepoint

One month after delivery

Method of measurement

Spielberger State-Trait Anxiety questionnaire

2

Description

Post-partum depression

Timepoint

One month after delivery

Method of measurement

Edinburgh Postnatal Depression Scale

3

Description

Fear of delivery

Timepoint

Immediately after delivery

Method of measurement

Visual Analogue Scale

4

Description
Delivery method satisfaction
Timepoint
Immediately after delivery
Method of measurement
Visual Analogue Scale

Intervention groups

1

Description
Intervention group 1: Pregnant women who were candidate for first vaginal delivery and had a good hypnotizability were recruited to hypnosis group. Pregnant mothers were trained for hypnosis since 32th week of pregnancy, in three 30-minute sessions (once in every 3 weeks) and delivery pleasing inductions and pain control conditioning were done for them. In delivery room, these inductions were applied by a trained midwife on pregnant mothers without using medicine or other analgesic and anesthetic methods.
Category
Other

2

Description
Intervention group 2: Pregnant women who were candidate for first vaginal delivery and received 25-50 milligrams (depending on patient weight on the basis of 1milligram for each kilogram of patient weight with at least 25 mg and at-most 50 mg) Pethidine (Iran, Broujerd, EXIR) during delivery to alleviate pain, were recruited in intravenous analgesic group.
Category
Treatment - Drugs

3

Description
Control group: Pregnant women who experienced their first vaginal delivery without any analgesic or anesthetic drugs.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Bent Al-Hoda Hospital
Full name of responsible person
Mohammad Reza Amirhasankhani
Street address
Bahar St.
City
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Razavi Khorasan
Postal code
9174685157
Phone
+98 51 3859 0051
Fax
+98 51 3851 8115
Email
bentolhodahospital@yahoo.com
Web page address
http://www.bent-hospital.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Vice research, Ghoreshi Building, Daneshgah St.
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9138813944
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+98 51 3841 1538
Email
vcresraech@mums.ac.ir
Grant name
Grant code / Reference number
970785
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mehdi Fathi
Position
Associate professor

Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Anesthesiology Department, Imam Reza Hospital, Imam Reza Sq., Ibn-e Sina Ave.
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Person responsible for scientific inquiries

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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
Yes - There is a plan to make this available
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
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
Evaluation of the effectiveness of self-hypnosis in pain relief during labor in pregnant women
When the data will become available and for how long
Study data are ready concerning the end of recruitment time and article is going to be prepared.
To whom data/document is available
Raw data are exclusively available for the study Authors
Under which criteria data/document could be used
on the basis of Mashhad University of Medical Sciences criteria
From where data/document is obtainable
Through study authors with maintaining confidential information
What processes are involved for a request to access data/document
on the basis of Mashhad University of Medical Sciences criteria
Comments