

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of hypnosis on the number and severity of uterine contractions, the latency of delivery and neonatal apgar score in women with preterm delivery in two groups of intervention (hypnosis) and control

Protocol summary

Study aim

Determining the effect of hypnosis on the number and severity of uterine contractions, the latency of labor and neonatal apgar score in women with preterm delivery in two groups of intervention (hypnosis) and control

Design

Two arm parallel groups randomized trial with preterm labor women and outcome assessment

Settings and conduct

Demographic characteristics and the anxiety questionnaire will be completed after the diagnosis of preterm labor. In eligible cases, random allocating will be performed. Pain will be assessed by the Visual Analogue Scale. Uterine Contractions will be recorded. Hypnosis will be done. At the time of termination of pregnancy in two groups, duration of delivery delay and neonate Apgar score and the mother's anxiety will be assessed by a collaborator (one person per shift). Data analysis and design contributors are blind to groups.

Participants/Inclusion and exclusion criteria

Preterm labor or if cervical dilatation is more than 1cm; No signs of severe depression; Dilatation less than 4cm while reception; No suicidal or self-harm thoughts; No signs of paranoid or anti-social personality; No signs of placental abruption; No signs of pre-eclampsia; No sign of fetal distress; No rupture of membranes; Maternal addiction; Maternal chronic -systemic diseases

Intervention groups

Mothers, in group A, receive routine treatments and there will be no medicinal interventions. In group B, hypnosis will be done in addition to routine treatments and the mothers will be taught self-hypnosis and self-hypnosis CDs will be distributed among mothers by the researcher. Hypnosis intervention will take 6 hours, on average, which will be done in four 1.5-hour sessions. The sessions will be conducted every day. Daily survey

on home exercises will be done by researcher.

Main outcome variables

uterine contraction; duration between start of treatment and delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161126031117N9**

Registration date: **2019-03-10, 1397/12/19**

Registration timing: **prospective**

Last update: **2019-03-10, 1397/12/19**

Update count: **0**

Registration date

2019-03-10, 1397/12/19

Registrant information

Name

Soghra Khani

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2019-06-20, 1398/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of hypnosis on the number and severity of uterine contractions, the latency of delivery and neonatal apgar score in women with preterm delivery in two groups of intervention (hypnosis) and control

Public title

The effect of hypnosis on preterm labor

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Preterm labor, recognizing regular uterine contractions by physical examination and recording uterine activity by Toco machine, during 25-37 weeks pregnancy or 24 weeks pregnancy if fetal weight estimation is more than 750gr or if cervical dilatation is more than 1cm No signs of severe depression Dilatation less than 4cm while reception No suicidal or self-harm thoughts No signs of paranoid personality, anti-social and psychosis disorders in clinical interviews by psychologist No signs of placental abruption in diagnostic ultrasonography imaging and clinical symptoms No signs of pre-eclampsia diagnosed by gynecologist Diagnostic criteria: Blood pressure equal or more than 140/90 mmHg after 20 weeks pregnancy and Proteinuria equal or more than 300 mg in 24 hours No sign of fetal distress is diagnosed by gynecologist. Diagnostic criteria: no variability patterns or decreased variability less than 5 beats per minute (bpm) with late deceleration or moderate-to-severe variable deceleration, or beat pattern less than 110bpm for 10minutes or more No rupture of membranes without any history of sudden and severe vaginal discharge diagnosed by experienced gynecologist through vaginal examination

Exclusion criteria:

Mother's addiction Maternal chronic -systemic diseases

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be divided into two A and B groups by drawing randomly. Each group contains 20 samples. Forty A and B cards will be put in a container. Every

participant, with inclusion criteria, will be asked to pick up a card. The taken card indicates the group. If two participants will be accepted simultaneously, the first drawing will be done and the second sample will not be participated in the study till the end of first participant's intervention (Hypnosis).

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Recording uterine contractions by Toco machine before and after Hypnosis

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mazandaran
University of Medical sciences University of Medic

Street address

Vice -Chancellor for Research of Mazandaran
University of Medical Sciences, Moalem Square

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Mazandaran

Postal code

4816715793

Approval date

2018-12-03, 1397/09/12

Ethics committee reference number

IR.MAZUMS.REC.97.3253

Health conditions studied**1****Description of health condition studied**

preterm labor

ICD-10 code

060

ICD-10 code description

preterm labour and delivery

Primary outcomes**1****Description**

Severity and number of uterine contractions

Timepoint

Before doing hypnosis, after doing hypnosis, and then

every one hour till dilatation 4cm and in control group every one hour till dilatation 4cm

Method of measurement

The on line analysis of the mechanical (TOCO)

2

Description

Amount of felt pain

Timepoint

Immediately after determining the groups and then after doing hypnosis in intervention group

Method of measurement

Visual Analog Scale (VAS).

3

Description

birth weight and Apgar score

Timepoint

Immediately after birth

Method of measurement

Digital scale and Apgar

4

Description

Age of pregnancy in termination time

Timepoint

In termination time

Method of measurement

According to the first day of the last menstrual period and ultrasonography imaging of early pregnancy

5

Description

Mother's anxiety

Timepoint

In termination time

Method of measurement

Pregnancy Related Anxiety Questionnaire (PRAQ 17)

Secondary outcomes

1

Description

time from intervention to delivery

Timepoint

before intervention and at delivery

Method of measurement

document the time.

Intervention groups

1

Description

. Intervention group: In this group, hypnosis will be done and if delivery hasn't occurred, in addition to routine treatments, the mothers will be taught self-hypnosis and

self-hypnosis CDs will be distributed among mothers by the researcher. Hypnosis intervention will take 7 hours, on average, which will be done in four 1.5-hour sessions. The sessions will be conducted every day. If the patient will be discharged, the sessions will be continued the day after discharge, in a suitable place. Daily survey on home exercises will be done by researcher through phone contact.

Category

Treatment - Other

2

Description

Control group: control group: Mothers in this group receive routine treatments and there will be no medicinal interventions

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Sari

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Sari 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
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Assistant Professor
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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The total potential data can be shared after unidentifiable people.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Data will only be available to researchers in academia and academia.

Under which criteria data/document could be used

Data will be provided to researchers in accordance with the principle of confidentiality.

From where data/document is obtainable

Sexual and Reproductive Health Research Center, Nasibeh Nursing and Midwifery school, Vesal street, AmirMazandarani Boulevard. khanisog343@gmail.com

What processes are involved for a request to access data/document

After emailing and sending the profile, it will be sent within a week.

Comments