

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of hypnosis on pain severity of the first stage of labor in primiparous women

Protocol summary

Study aim

The purpose of this study is to investigate the effect of hypnosis on the severity of pain in the first stage of labor in primiparous women.

Design

In this study, 64 pregnant women referred to health centers in Sabzevar who are eligible to enter the study are selected. Participants are randomly divided into intervention and control groups and each code is assigned to hide the intervention group of each participant.

Settings and conduct

The both Intervention and control groups from the 32nd week of gestation are trained for 8 sessions (twice a week) in an educational class at Mobini Hospital in Sabzevar city. The control group is trained about stages of delivery, prenatal care, risk symptoms, baby care and ... by a midwifery master and in the intervention group, in addition, hypnosis is trained by a single hypnotherapist and hypnosis conditioning is done. During the first stage of labor, a hypnotherapist along with a midwife who has been trained in the field of hypnosis, are present in place and carries out conditioning procedures for the intervention group. In the control group, routine care is performed during labor. The Visual Analog Scale Questionnaire for pain measurement is completed in both groups during labor and after delivery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: nulliparous women age of 23 to 35 years gestational age of 30 to 32 weeks at the start of the study normal fetus in ultrasound scans not having contraindications for vaginal delivery having at least primary education Singleton pregnancy having normal BMI Exclusion criteria: history of psychotherapy or mental disease cigarette, opioid, and alcohol addiction history of repetitive abortion and infertility.

Intervention groups

Intervention group from the 32nd week of gestation are hypnotized by hypnotherapist for 6 sessions (weekly).

During the first stage of labor, hypnosis is also done by a hypnotherapist.

Main outcome variables

Severity of labor pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161222031519N2**

Registration date: **2018-04-04, 1397/01/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-04, 1397/01/15**

Update count: **0**

Registration date

2018-04-04, 1397/01/15

Registrant information

Name

Zahra Zare

Name of organization / entity

Sabzevar University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 4401 8301

Email address

zarez@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
The effect of hypnosis on pain severity of the first stage of labor in primiparous women
Public title
The effect of hypnosis on the severity of labor pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria: first pregnancy, age of 20 to 35 years, gestational age 30- 32 weeks at the beginning of the study, healthy and normal fetus in ultrasound survey , not having detectable barriers to normal delivery, singleton pregnancy, no history of mental disorder, no addiction to cigarettes, drugs and alcohol.
Exclusion criteria:
Termination of pregnancy for any reason before the end of the sessions Indication for cesarean delivery
Age
From **20 years** old to **35 years** old
Gender
Female
Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
The research units were divided into two intervention and control groups by simple randomization method.
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 Sabzevar University of Medical Sciences

Street address

Sabzevar University of Medical Sciences, Boulevard Nuclear Martyrs,

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114- 96179131

Approval date

2015-04-21, 1394/02/01

Ethics committee reference number

IR.MEDSAB.REC.1394.69

Health conditions studied

1

Description of health condition studied

Relationship hypnosis with pain severity of first stage of labor in primiparous women.

ICD-10 code

E084, E080

ICD-10 code description

single spontaneous delivery

Primary outcomes

1

Description

Severity of labor pain

Timepoint

Study of pain severity 4 times in the first stage of labor in dilatation of 4.6, 8 and 10 cm

Method of measurement

VAS

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group": from the 32 weeks of gestational age for 8 sessions (twice a week), they are trained about stages of delivery, prenatal care, risk symptoms, baby care and ... by a midwifery master. In addition, hypnosis is trained by a single hypnotherapist and conditioning hypnosis is done. During the first stage of labor, a hypnotherapist is present at the site and carries out the conditioning process.

Category

Treatment - Other

2

Description

Control group: During labour, they receive routine care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mobini Hospital of Sabzevar

Full name of responsible person

Zahra Zare

Street address

Mobini Hospital, Kashefi Street, Sabzevar

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613856776

Phone

+98 51 4423 8100

Fax

+98 51 4422 1002

Email

zarez@medsab.ac.ir

Web page address

<http://www.medsab.ac.ir/index.aspx?siteid=1&pageid=159>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr Fereshteh Ghorat

Street address

Sabzevar, Nuclear Martyrs Boulevard, Sabzevar
University of Medical Sciences

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913112

Phone

+98 51 4401 8319

Fax

+98 51 4422 1002

Email

drghorat@gmail.com

Web page address

<http://www.medsab.ac.ir/index.aspx?siteid=1&pageid=2085>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Zahra Zare

Position

Instructor of Midwifery, Faculty of Nursing and
Midwifery, Sabzevar University of Medical Sciences,

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Sabzevar, Nuclear Martyrs Boulevard Sabzevar
University of Medical Sciences, School of Nursing and
Midwifery

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613856776

Phone

+98 51 4423 8100

Fax

+98 51 4422 1002

Email

zarez@medsab.ac.ir

Web page address

<http://www.medsab.ac.ir/index.aspx?fkeyid=&siteid=1&pageid=7003>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Zahra Zare

Position

Instructor of Midwifery, Faculty of Nursing and
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Midwifery

City

Sabzevar

Province

Razavi Khorasan

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Email

zarez@medsab.ac.ir

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<http://www.medsab.ac.ir/index.aspx?fkeyid=&siteid=1&pageid=7003>

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Fax

+98 51 4422 1002

Email

zarez@medsab.ac.ir

Web page address

<http://www.medsab.ac.ir/index.aspx?siteid=1&pageid=159>

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

Sabzevar University of Medical Sciences

Full name of responsible person

Zahra Zare

Position

مربی گروه مامایی، دانشکده پرستاری و مامایی، دانشگاه علوم
پزشکی سبزوار، سبزوار، ایران

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Mobini Hospitol, Kashefi Street, Sabzevar

City**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