Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing effect of self-hypnosis versus no hypnosis on delivery pain in pregnant women: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of self-hypnosis versus no hypnosis on delivery pain in pregnant women

Design
A randomized clinical trial, phase 2, including 640 patients

Settings and conduct
The eligible pregnant women who will refer to Fatemieh Hospital during the study period will be enrolled into the trial

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 40 years; gestational age of 28 months or over Exclusion criteria: Chronic diseases such as diabetes or cardiovascular diseases; gestational complications such as gestational diabetes or preeclampsia or preterm labor

Intervention groups
Intervention group: Normal delivery with self-hypnosis train to pregnant woman during 5 one-hour sessions Control group: Normal delivery without hypnosis

Main outcome variables
Primary outcome: Assessing the severity of pain during delivery using visual analog scale (VAS)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N199**
Registration date: **2017-12-05, 1396/09/14**
Registration timing: **prospective**

Last update: **2017-12-05, 1396/09/14**
Update count: **0**

Registration date
2017-12-05, 1396/09/14

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-06, 1396/09/15

Expected recruitment end date
2019-12-06, 1398/09/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing effect of self-hypnosis versus no hypnosis on delivery pain in pregnant women: a randomized clinical trial

Public title
Comparing effect of self-hypnosis versus no hypnosis on delivery pain in pregnant women

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age of 18 to 40 years Gestational age of 28 months or over

Exclusion criteria:
Chronic diseases such as diabetes or cardiovascular diseases Gestational complications such as gestational diabetes or preeclampsia or preterm labor

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **640**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of the patients to the intervention and control groups by writing the names of intervention and control on two sheets and then taking the sheets randomly

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 Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2017-11-04, 1396/08/13

Ethics committee reference number
IR.UMSHA.REC.1396.522

Health conditions studied

1

Description of health condition studied
Normal delivery

ICD-10 code
O60.2

ICD-10 code description
Term delivery with preterm labor

Primary outcomes

1

Description
Assessing the severity of pain

Timepoint
During delivery

Method of measurement
Using visual analog scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Normal delivery with self-hypnosis train to pregnant woman during 5 one-hour sessions

Category
Prevention

2

Description
Control group: Normal delivery without hypnosis

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemieh Hospital

Full name of responsible person
Mohammad Rasool Abdoli

Street address
Fatemieh Hospital, Pasdaran Ave.

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Hamedan 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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Master of Clinical Psychology
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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