

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Effect of using breathing techniques versus not using on anxiety, duration and severity of labor pain in primiparous women: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of using breathing techniques versus not using on anxiety, duration and severity of labor pain in primiparous women

Design

This is a randomized clinical trial, in which 140 eligible primiparous women will be randomly assigned to the intervention and control groups

Settings and conduct

The primiparous women who will refer to Health Centers of Tuyserkan City during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: age of 18 to 35 years; gestational age of 30 to 32 weeks; singleton; literate; mild to moderate anxiety score. Exclusion criteria: Chronic disease such as hypertension, diabetes, asthma, cardiovascular diseases, and respiratory diseases; pregnancy complications such as gestational diabetes, preeclampsia, bleeding, placenta previa, signs of preterm labor; oligohydramnios and polyhydramnios; psychological disorders and stress; psychological disorders and stress; macrosomia.

Intervention groups

Intervention group: routine education and care before childbirth plus educationa session of how to use breathing techniques one hour weekly for 4 weeks.
Control group: just routine education and care before childbirth.

Main outcome variables

Anxiety; the severity of labor pain; the duration of labor pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N240**

Registration date: **2018-10-07, 1397/07/15**

Registration timing: **prospective**

Last update: **2018-10-07, 1397/07/15**

Update count: **0**

Registration date

2018-10-07, 1397/07/15

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of using breathing techniques versus not using on

anxiety, duration and severity of labor pain in primiparous women: a randomized clinical trial

Public title

Effect of using breathing techniques versus not using on anxiety, duration and severity of labor pain in primiparous women: a randomized clinical trial

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age range: 18 to 35 years old Gestational age: 30 to 32 weeks Singleton pregnancy Being literate Mild to moderate anxiety score

Exclusion criteria:

Chronic disease such as hypertension, diabetes, asthma, cardiovascular diseases, and respiratory diseases Pregnancy complications such as gestational diabetes, preeclampsia, bleeding, Placenta Previa, signs of preterm labor oligohydramnios and polyhydramnios; psychological disorders and stress Psychological disorders and stress Macrosomia

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization

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

2018-09-22, 1397/06/31

Ethics committee reference number

IR.UMSHA.REC.1397.429

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

2

Description of health condition studied

labor pain

ICD-10 code

R10.2

ICD-10 code description

Pelvic and perineal pain

Primary outcomes

1

Description

Assessing anxiety

Timepoint

During labor

Method of measurement

By using Spielberger questionnaire

2

Description

Assessing the severity of labor pain

Timepoint

During labor

Method of measurement

By using Visual Analog Scale (VAS)

3

Description

Assessing the duration of labor pain

Timepoint

During labor

Method of measurement

By taking history

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine education and care before childbirth plus educationa session of how to use breathing techniques one hour weekly for 4 weeks

Category

Prevention

2

Description

Control group: Just routine education and care before childbirth

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers of Tuyserkan City

Full name of responsible person

Faezeh Fazli

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

faezehbehnam7@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

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

Hamedan University of Medical Sciences

Full name of responsible person

Faezeh Fazli

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.
00988138380572

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

faezehbehnam7@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Parisa Parsa

Position

Community Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

pparsa@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of

Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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