

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Studying the impacts of the combination of effective methods compared with doula on reducing anxiety and pain of mothers in childbirth in the Jam Tohid Hospital in 2015

Protocol summary

Summary

Objective: To compare the collective impact of effective methods on reducing anxiety and pain of mothers in childbirth with the effect of doula in the Jam Tohid hospital in 2015 Study Type: This is an interventional study will be conducted on two groups who will receive a combination of effective methods and those who only have doula. This study will be carried out in the Jam Tohid Hospital Affiliated to Bushehr University of Medical Sciences. Inclusion criteria: Nulliparous pregnant women aged 16-44; Having a single fetus; Not having any pregnancy complications as well as mental diseases; At least 32 weeks of gestational age Type of intervention and the time of intervention: The studied women will be allocated randomly to two groups: study group (the combination of effective methods) and control group (doula). During pregnancy, in coordination with the mother-friendly hospital heads, several pregnancy and childbirth preparation classes (6 sessions with about 105 minutes within a week of each other will be held by the by the researcher and his colleagues which are about training neuromuscular exercises, relaxation, proper breathing, concentration exercises and also the appropriate positions in childbirth. Intervention outcomes: Reduced pain and anxiety of labor

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015083123837N1**
Registration date: **2015-10-26, 1394/08/04**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-10-26, 1394/08/04

Registrant information

Name

Ramin Ravangard

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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+98 912 224 3772

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the impacts of the combination of effective methods compared with doula on reducing anxiety and pain of mothers in childbirth in the Jam Tohid Hospital in 2015

Public title

Studying the impacts of the combination of effective methods compared with doula on reducing anxiety and pain of mothers in childbirth in the Jam Tohid Hospital in

2015

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion Criteria: - Being Iranian; - Age between 16 and 44; - First pregnancy; - At least 32 weeks of gestational age; - Lack of pregnancy complications; - Having a live fetus; - Having a single fetus; - Start spontaneous contractions; - Intact sac; - No pelvic restraint; - No history of hospitalization due to complications of pregnancy; - No history of diseases such as thyroid, and diseases related to the kidney, heart, liver, diabetes, and lack of psychiatric diseases. Exclusion Criteria: - Fetal macrosomia; - The studied pregnant women's unwillingness to continue their cooperation with the researcher and participation in the intervention; - Fetal anomaly detection during the study; - Onset of labor before or after term; - Fetal distress; - Premature rupture of membranes; - The use of pain relievers; - The occurrence of any complications during labor and delivery and the need for cesarean section.

Age
From **16 years** old to **44 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
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

The Ethics Committee in Biomedical Research, Shiraz
University of Medical Sciences, Cose: EC UMS S I

Street address

Iran

City

Shiraz

Postal code

7134814336

Approval date

2015-08-19, 1394/05/28

Ethics committee reference number
IR.SUMS.REC.1394.95

Health conditions studied

1

Description of health condition studied

Single spontaneous delivery

ICD-10 code

o80

ICD-10 code description

Single spontaneous delivery

Primary outcomes

1

Description

Pain

Timepoint

During delivery

Method of measurement

McGill Pain Questionnaire

2

Description

Anxiety

Timepoint

Before and during delivery

Method of measurement

Spielberger State-Trait Anxiety Inventory Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control: Having Doula during delivery

Category

Other

2

Description

Intervention: During pregnancy, in coordination with the mother-friendly hospital heads, several pregnancy and childbirth preparation classes (6 sessions with about 105 minutes within a week of each other) will be held by the researcher and his colleagues which are about training neuromuscular exercises, relaxation, proper breathing, concentration exercises and also the appropriate positions in childbirth.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Tohid hospital in Jam

Full name of responsible person

Dr. Ravangard

Street address

Bushehr, Jam, Shahrak Tohid

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

Iran

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Assistant Prof.

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty