Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Country
Iran (Islamic Republic of)

Phone
+98 912 224 3772

Email address
ravangard@sums.ac.ir

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

Befor 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 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
Dr. Ramin Ravangard
Position
Assistant Prof.
Other areas of specialty/work
Street address
Iran
City
Shiraz
Postal code
7134814336
Phone
+98 71 3234 0774
Fax
+98 71 3234 0039
Email
ravangard@sums.ac.ir; ra_ravangard@yahoo.com
Web page address
sums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Ramin Ravangard
Position
Assistant Prof.
Other areas of specialty/work
Street address
Iran
City
Shiraz
Postal code
7134814336
Phone
+98 71 3234 0774
Fax
+98 71 3234 0039
Email
ravangard@sums.ac.ir; ra_ravangard@yahoo.com
Web page address
sums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Ramin Ravangard
Position
Assistant Prof.
Other areas of specialty/work
Street address
Iran
City
Shiraz
Postal code
7134814336
Phone
+98 71 3224 0774
Fax
+98 71 3234 0039
Email
ravangard@sums.ac.ir; ra_ravangard@yahoo.com
Web page address
sums.ac.ir

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