Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessing the effect of relaxation techniques on fetal outcomes in high risk pregnant women with sleep breathing disorders

Protocol summary

Summary

Among high risk pregnant women 180 cases that their scores from Peterborough Sleep Quality Index questionnaire are 5 or more will be selected. The subjects are randomly divided into 2 groups (intervention and control group). Relaxation techniques will be taught to intervention group. The intervention group will carry out the relaxation techniques for 8 sessions while the control group will be received routine care only. In the end of intervention, both the intervention and the control group will fill Peterborough Sleep Quality Index questionnaire again. Furthermore such variables like newborn weight and apgar score, PH and Interleukin concentration of umbilical blood samples will be measured after delivery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013092310327N5**
Registration date: **2014-09-13, 1393/06/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-09-13, 1393/06/22

Registrant information

Name
Farideh Vaziri
Name of organization / entity
Shiraz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2013-12-21, 1392/09/30

Expected recruitment end date

2014-08-21, 1393/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of relaxation techniques on fetal outcomes in high risk pregnant women with sleep breathing disorders

Public title

the effecst of relaxation techniques on fetal outcomes in high risk pregnant women with sleep breathing disorders

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: people tend to have the cooperation;19 to 35 year old pregnant women ; pregnant women with sleep breathing disorder diagnosed by Pitsburg questionnaire; third trimester pregnant women admitted with the diagnosis of gestational diabetes requires insulin; type II diabetes and preeclapsia; having pregnancy more than 28 weeks; not to be drug and substance abuser; singleton l pregnancy - exclusion criteria: having chronic disease; fetal abnormalities in ultrasound; abnormal vaginal bleeding

Age

From **19 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Shiraz University of Medical Sciences

Street address

Central building Shiraz University of Medical Sciences, Zand Ave, Shiraz

City

Shiraz

Postal code

713451978

Approval date

2013-12-21, 1392/09/30

Ethics committee reference number

92-6814

Health conditions studied

1

Description of health condition studied

Fetal outcomes in high risk pregnant women with sleep disordered breathing

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Interleukin 6

Timepoint

After Delivery

Method of measurement

Laboratory Kit

2

Description

Apgar score

Timepoint

Birth Time

Method of measurement

Apgar Score category

3

Description

newborn Weight

Timepoint

Birth Time

Method of measurement

Weight scales

4

Description

PH

Timepoint

After Delivery

Method of measurement

Laboratory Kit

Secondary outcomes

1

Description

Sleep Breathing Disorder

Timepoint

Before And After Intervention

Method of measurement

Pitsburg Sleep Disorder Index Questionnaire

Intervention groups

1

Description

In intervention group: Muscle relaxation techniques for 8 sessions

Category

Treatment - Other

2

Description

In the control group: routine care

Category

Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hafez Hospital
Full name of responsible person
Mona Dorakvandi
Street address
The beginning of Chamran Blv, Shiraz, Fars
City
Shiraz

2

Recruitment center
Name of recruitment center
Hazrat Zeinab Hospital
Full name of responsible person
Mona Dorakvandi
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Defa Moqadas Square, Shiraz, Fars
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Shiraz University of Medical Sciences
Full name of responsible person
Gholam Reza Hatam
Street address
7th Floor, Shiraz University of Medical Sciences, Central building , Zand Ave, Shiraz
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of 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
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Person responsible for updating data

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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