

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effectiveness of progressive muscle relaxation on maternal and neonatal outcomes on primiparous women with preeclampsia in Kamali hospital, Karaj, Iran 2019-2020

Protocol summary

Study aim

Evaluation of the effectiveness of progressive muscle relaxation on maternal and neonatal outcomes on primary parous women with preeclampsia

Design

This study is a randomized clinical trial with two parallel control and intervention groups. Participants (88 eligible women with inclusion criteria) will be entered the study through convenient sampling. Allocation will be done using block randomization.

Settings and conduct

Pre-natal and Emergency wards of Kamali hospital in Karaj

Participants/Inclusion and exclusion criteria

inclusion criteria: 1-primiparous women with 26-34 weeks gestational age 2-singleton pregnancy 3-non-severe preeclampsia 4-low risk results in the first and second trimesters fetal screenings 5-persian race and at least having reading and writing literacy. Exclusion criteria: 1- physical and mental illnesses (such as cardio-respiratory disease, diabetes mellitus and gestational diabetes, seizure, depression, anxiety disorders ,etc) 2- history of infertility and/or repeated miscarriage 3- vaginal hemorrhage and/or leaking amniotic fluid and/or uterine contractions 4- recent severe stress and/or anxiety 5- intrauterine growth restriction 6- usage of alcohol and/or cigarettes and/or drugs

Intervention groups

In the intervention group, in addition to routine prenatal care, progressive muscle relaxation will be performed and the control group will receive only routine prenatal care

Main outcome variables

blood pressure, proteinuria, fasting blood sugar, maternal weight gain, ammonium fluid index, gestational age at delivery, becoming severe preeclampsia, fetal movements, and fetal heart rate, I APGAR score, and

neonatal anthropometric indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180110038302N6**

Registration date: **2020-06-27, 1399/04/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-27, 1399/04/07**

Update count: **0**

Registration date

2020-06-27, 1399/04/07

Registrant information

Name

Mansoureh Yazdkhasti

Name of organization / entity

Alborz University medical science

Country

Iran (Islamic Republic of)

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+98 21 4401 8856

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-19, 1398/12/29

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of progressive muscle relaxation on maternal and neonatal outcomes on primiparous women with preeclampsia in Kamali hospital, Karaj, Iran 2019-2020

Public title
Evaluation of the effectiveness of progressive muscle relaxation on maternal and neonatal outcomes on primary parous women with preeclampsia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
primary parous women with 26-34 weeks gestational age singleton pregnancy non-severe preeclampsia criterias low risk results in the first and second trimester fetal screenings persiane race and at least having reading and writing literacy
Exclusion criteria:
physical and mental illnesses (such as cardio-respiratory disease, diabetes mellitus and gestational diabetes, seizure, depression, anxiety disorders ,etc) history of infertility and/or repeated miscarriage vaginal hemorrhage and/or leaking amniotic fluid and/or uterine contractions recent severe stress and/or anxiety intrauterine growth restriction usage of alcohol and/or cigarettes and/or drugs

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Balance Randomization 4th is accomplished with software. In this method size of the whole Blocks are equal. In this study with 88 sample sizes, blocks are 22 th and the size of each block is 4 th .The number of participants in the control and intervention group is equal(44 in each group).

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 Alborz University of Medical Sciences

Street address

West Buali street, Alborz University of Medical Sciences

City

Karaj

Province

Alborz

Postal code

sara_ghorbannejad25@

Approval date

2020-05-01, 1399/02/12

Ethics committee reference number

IR.ABZUMS.REC.1399.033

Health conditions studied

1

Description of health condition studied

Preeclampsia

ICD-10 code

O15.00

ICD-10 code description

Eclampsia in pregnancy, unspecified trimester

Primary outcomes

1

Description

Blood pressure

Timepoint

before and after 6 weeks of intervention

Method of measurement

mercury sphygmo manometer

Secondary outcomes

1

Description

proteinuria

Timepoint

before and after 6 weeks of intervention

Method of measurement

collect a 24-hr clean midstream urine sample

2

Description

fasting blood sugar

Timepoint

before and after 6 weeks of intervention

Method of measurement

glucometer

3

Description

maternal weight gaining

Timepoint

before and after 6 weeks of intervention

Method of measurement

digital scale

4

Description

turn to severe preeclampsia

Timepoint

after 6 weeks of intervention

Method of measurement

collect a 24-hr clean midstream urine sample and mercury sphygmo manometer

5

Description

delivery gestational age

Timepoint

after 6 weeks of intervention

Method of measurement

hospital document

6

Description

amniotic fluid index

Timepoint

before and after 6 weeks of intervention

Method of measurement

ultra sonogram

7

Description

fetal movement

Timepoint

before and after 6 weeks of intervention

Method of measurement

none stress test

8

Description

fetal heart rate

Timepoint

before and after 6 weeks of intervention

Method of measurement

none stress test

9

Description

apgar score

Timepoint

after 6 weeks of intervention

Method of measurement

hospital document

10

Description

antropometric index

Timepoint

after 6 weeks of intervention

Method of measurement

hospital document

Intervention groups

1

Description

Intervention group: using progressive muscle relaxation, which is done for 12 sessions by 6 weeks and 2 sessions per week

Category

Other

2

Description

Control group:beside routine prenatal care,No action will be taken for the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali hospital

Full name of responsible person

Mansooreh Yazdkhusti

Street address

West Buali street, Alborz University of Medical Sciences

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3149969415

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Email

Mansoyazd@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Mansooreh Yazdkhusti

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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

Alborz 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**

Alborz medical science university

Full name of responsible person

Mansooreh Yazdkhusti

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Alborz University of Medical Sciences

Full name of responsible person

Mansooreh Yazdkhusti

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact**Name of organization / entity**

Alborz University of Medical Sciences

Full name of responsible person

Sara Ghorbannejad

Position

Midwife

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable