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, l 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

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Iran (Islamic Republic of)

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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 frist 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

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Sponsors / Funding sources

1

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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
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Mansooreh Yazdkhusti
Position
Associate professor
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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