Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The effect of a period of combined exercise training in overweight pregnant women on inflammatory factor (TNF-α) and Mean Arterial Pressure

Protocol summary

Study aim

The effect of a period of combined exercise training in overweight pregnant women on inflammatory factor (TNF-α) and Mean Arterial Pressure

Design

The sampling method is convenient, including overweight pregnant women at 11-16 w gestational visiting hospital prenatal care unit. . By using random digit table, participating mothers are randomly allocated to two study groups: intervention(exercise) group and control group.The sample size is 14 people for each group.

Settings and conduct

A demographic/reproductive questionnaire is completed in person.TNF-a levels and blood pressure are measured and recorded.Pregnant women are trained about exercises by training expert and researcher.The control group will continue their routine physical activity without especial plan. Besides checking the Gestational Diabetes screening at 24-28 w, TNF-a and blood pressure are measured and MAP is calculated.The blood pressure is recorded in the last prenatal care of both groups.TNF-a level is measured and recorded at delivery time.

Participants/Inclusion and exclusion criteria

1-Pregnant women with 11-16 weeks of gestational age
2-Body Mass Index (BMI) of 25 -29.9 Kg / m2 before pregnancy or in the first prenatal visit

Intervention groups

The intervention protocol for intervention group includes: Aerobic exercise(walking) and stretching exercise(for muscle stretching). The exercise program will start from 16 w gestational and continue until 35 w gestational.To determine intensity,speaking test will be used. Control group during study period,will continue usual physical activity without specific training program.

Main outcome variables

TNF-α, Mean Arterial Pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190410043222N1**
Registration date: **2019-05-02, 1398/02/12**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-02, 1398/02/12**
Update count: **0**

Registration date

2019-05-02, 1398/02/12

Registrant information

Name
Mona Pourmohammad Eilanjegh

Name of organization / entity
Tarbiat Modares University

Country
Iran (Islamic Republic of)

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mona_pou@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of a period of combined exercise training in overweight pregnant women on inflammatory factor (TNF-α) and Mean Arterial Pressure

Public title
The effect of combined exercises in pregnancy and TNF-α levels and Mean Arterial Pressure
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women in 11-16 weeks of gestation Body Mass Index (BMI) of 25 -29.9 Kg / m2 before pregnancy or in the first prenatal visit Mother's age 18-35 years old Single pregnancy Residing in Tehran Iranian citizenship
Exclusion criteria:
Chronic and systemic diseases Any of the absolute and relative contraindications of pregnancy exercises according to ACOG Guideline Diabetes (type I, type II) Use of psychological drugs, Opiate products or alcohol
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **28**
Randomization (investigator's opinion)
Randomized
Randomization description
Participating mothers are randomly assigned into two groups (intervention and control) based on entry number in the study and using the random numbers table
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Research Ethics Committee
Street address
Jalal Al-Ahmad Highway
City
Tehran
Province
Tehran
Postal code
1411713116
Approval date
2019-01-05, 1397/10/15
Ethics committee reference number
IR.MODARES.REC.1397.190

Health conditions studied

1

Description of health condition studied
Pregnancy
ICD-10 code
O13.9
ICD-10 code description
Gestational [pregnancy-induced] hypertension without significant proteinuria, unspecified trimester

2

Description of health condition studied
overweight
ICD-10 code
O99.210
ICD-10 code description
Obesity complicating pregnancy, unspecified trimester

Primary outcomes

1

Description
TNF-α
Timepoint
11-16 weeks , 24-28 weeks and delivery time
Method of measurement
Blood sample of venous

2

Description
Mean Arterial Pressure
Timepoint
11-16, and 24-28 weeks of gestation, labor
Method of measurement
Measuring systolic and diastolic blood pressure

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The group, after training exercise , begin a Specific combined exercise schedule including

aerobic, resistance and endurance activities from the 16 weeks of gestational age.The combination of exercises will be based on the gestational age. At each prenatal visit, the exercise program for 4 weeks later will be given to pregnant women. weekly How to do exercises, will be controlled by researcher trough phone call . Exercises will be continued until 35 weeks of gestational age. Routine prenatal care visits will be done during pregnancy. Pregnant women whenever they want, they can be removed from the intervention group. If any of the interventions group exits, a new sample will be replaced.

Category

Prevention

2

Description

The Control group :This group will be had usual physical activity during pregnancy. Routine prenatal care visits will be done during pregnancy. Pregnant women whenever they want, they can be removed from the control group. If any of the control group exits, a new sample will be replaced.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sarem hospital

Full name of responsible person

Mona Pourmohammad Eilanjegh

Street address

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2

Recruitment center

Name of recruitment center

Najmiyeh Hospital

Full name of responsible person

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Phone

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Web page address

https://najmiyeh.bmsu.ac.ir/Portal/Home/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Yaghoub Fathollahi

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Jalal Al Ahamd Highway

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Email

moghaddamb@modares.ac.ir

Web page address

http://www.modares.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tarbiat Modares University

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

Tarbiat Modares University

Full name of responsible person

Lida Moghaddam-Banaem

Position

Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
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Person responsible for scientific inquiries

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Lida Moghaddam-Banaem
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Person responsible for updating data

Contact
Name of organization / entity
Tarbiat Modares University
Full name of responsible person
Mona Pourmohammad Eilanjegh
Position
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Latest degree
Bachelor
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mona_pou@modares.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Data will be published in total not individual levels; because of the objectives of the study there is no need to publish individual characteristics and data of the participants
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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Outcomes of the study will be shared.
When the data will become available and for how long
6 months after results publication, data will be shared.
To whom data/document is available
All researchers who work in women health field can access this data.
Under which criteria data/document could be used
Data is applicable to use by all midwifery/ obstetrics personnel in cases of overweight pregnant women.
From where data/document is obtainable
Primary Investigator
What processes are involved for a request to access data/document
Emailing the request to the primary investigator
Comments