

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 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 Eilanjeh

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 3857

Email address

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	Tehran
Scientific title	Province
The effect of a period of combined exercise training in overweight pregnant women on inflammatory factor (TNF- α) and Mean Arterial Pressure	Tehran
Public title	Postal code
The effect of combined exercises in pregnancy and TNF- α levels and Mean Arterial Pressure	1411713116
Purpose	Approval date
Prevention	2019-01-05, 1397/10/15
Inclusion/Exclusion criteria	Ethics committee reference number
Inclusion criteria:	IR.MODARES.REC.1397.190
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	Health conditions studied
Exclusion criteria:	1
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	Description of health condition studied
Age	Pregnancy
From 18 years old to 35 years old	ICD-10 code
Gender	O13.9
Female	ICD-10 code description
Phase	Gestational [pregnancy-induced] hypertension without significant proteinuria, unspecified trimester
N/A	2
Groups that have been masked	Description of health condition studied
No information	overweight
Sample size	ICD-10 code
Target sample size: 28	O99.210
Randomization (investigator's opinion)	ICD-10 code description
Randomized	Obesity complicating pregnancy, unspecified trimester
Randomization description	Primary outcomes
Participating mothers are randomly assigned into two groups (intervention and control) based on entry number in the study and using the random numbers table	1
Blinding (investigator's opinion)	Description
Not blinded	TNF- α
Blinding description	Timepoint
Placebo	11-16 weeks , 24-28 weeks and delivery time
Not used	Method of measurement
Assignment	Blood sample of venous
Other	2
Other design features	Description
Secondary Ids	Mean Arterial Pressure
empty	Timepoint
Ethics committees	11-16, and 24-28 weeks of gestation, labor
1	Method of measurement
Ethics committee	Measuring systolic and diastolic blood pressure
Name of ethics committee	Secondary outcomes
National Research Ethics Committee	empty
Street address	Intervention groups
Jalal Al-Ahmad Highway	1
City	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 through 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 Eilanjeh

Street address

Phase 3, Ekbatan complex, Sarem Hospital

City

Tehran

Province

Tehran

Postal code

1396956111

Phone

+98 21 4467 0888

Fax

Email

saremfertilityinfo@gmail.com

Web page address

http://saremfertility.com

2

Recruitment center

Name of recruitment center

Najmijeh Hospital

Full name of responsible person

Mona Pourmohammad Eilanjeh

Street address

Jomhoori Ave. Hafez Crossroad

City

Tehran

Province

Tehran

Postal code

1139817813

Phone

+98 21 6670 7071

Email

najmijeh@bagh.ac.ir

Web page address

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

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Yaghoob Fathollahi

Street address

Jalal Al Ahamd Highway

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 3857

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
Street address
Jalal Al Ahmad Highway
City
Tehran
Province
Tehran
Postal code
1411713116
Phone
+98 21 8288 3857
Email
moghaddamb@modares.ac.ir
Web page address
<http://www.modares.ac.ir>

Person responsible for scientific 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
Street address
Jalal Al Ahmad Highway
City
Tehran
Province
Tehran
Postal code
1411713116
Phone
+98 21 8288 3857
Email
moghaddamb@modares.ac.ir
Web page address
<http://www.modares.ac.ir>

Person responsible for updating data

Contact

Name of organization / entity
Tarbiat Modares University
Full name of responsible person
Mona Pourmohammad Eilanjeh
Position

student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Jalal Ahmad Highway
City
Tehran
Province
Tehran
Postal code
1411713116
Phone
+98 82883857
Email
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