Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of a period of combined exercise training in overweight pregnant women on level ant inflammatory factor interlukin10

Protocol summary

Study aim
The effect of a period of combined exercise training in overweight pregnant women on ant inflammatory factor Interleukin10

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. Interleukin10 level is 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, Interleukin10 is measured. Interleukin10 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
Interlukin10

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200415047084N1**
Registration date: **2021-03-23, 1400/01/03**
Registration timing: **retrospective**

Last update: **2021-03-23, 1400/01/03**
Update count: **0**

Registration date
2021-03-23, 1400/01/03

Registrant information

Name
Nahid Zendehbil

Name of organization / entity
Tarbiat Modares University

Country
Iran (Islamic Republic of)

Phone
+98 28 3524 9212

Email address
nahidzendehbil@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-30, 1399/04/10

Expected recruitment end date
2021-03-19, 1399/12/29

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 level ant inflammatory factor interlukin10

Public title
The effect of a period of combined exercise training in overweight pregnant women on level ant inflammatory factor interlukin10

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Iranian citizenship Pregnant women with 11-16 weeks of gestational age Mother's age 18-35 years old Residing in Tehran Body Mass Index (BMI) of 25 -29.9 Kg / m2 before pregnancy or in the first prenatal visit Single pregnancy

Exclusion criteria:
Chronic and systemic diseases Diabetes (type I, type II) Use of psychological drugs،Opiate products or alcohol Any of the absolute and relative contraindications of pregnancy exercises according to ACOG Guideline

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **28**

Randomization (investigator's opinion)
N/A

Randomization description

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
National Research Ethics Committee

Street address
Jalal Al-Ahmad Highway

City
Tehran

Province
Tehran

Postal code
1411713116

Approval date
2020-03-10, 1398/12/20

Ethics committee reference number
IR.MODARES.REC.1399.001

Health conditions studied

1

Description of health condition studied
Overweight

ICD-10 code
O99.210

ICD-10 code description
Obesity complicating pregnancy, unspecified trimester

Primary outcomes

1

Description
Interleukin 10 anti-inflammatory factor

Timepoint
Week 16-11 of pregnancy, Week 28-24 of pregnancy and delivery time

Method of measurement
Venous blood sample

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
Nahid zendehbil

Street address
Ekbatan town, Sarem specialized and subspecialty hospital

City
Tehran

Province
Tehran

Postal code
1396956111

Phone
+98 21 4467 0888

Email
saremfertilityinfo@gmail.com

Web page address
http://saremfertility.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tarbiat Modares University

Full name of responsible person
Yaqub Fath Elahi

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

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 mogaddam bnaem

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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tarbiat Modares University

Full name of responsible person
Lida mogadam bnaem

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 82883857

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
Nahid zendehbil
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Jalal Al-Ahmad Highway
City
Tehran
Province
Tehran
Postal code
1411713116
Phone
+98 82883857
Email
Nahidzendehbil@yahoo.com

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
The data will be reported collectively because there is no need to publish participants' personal characteristics and data according to the study objectives.
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
Information about the consequences will be shared.
When the data will become available and for how long
Information will be shared 6 months after the results are published.
To whom data/document is available
All researchers working in the field of women's health can access this information
Under which criteria data/document could be used
For midwives and midwives, it can be used by overweight pregnant women
From where data/document is obtainable
The main researcher of the project
What processes are involved for a request to access data/document
Email containing the request for the original project researcher
Comments