

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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 Zندهbil

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 28 3524 9212

Email address

nahidzندهbil@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 interleukin10

Public title

The effect of a period of combined exercise training in overweight pregnant women on level ant inflammatory factor interleukin10

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

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1396956111

Phone

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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

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Tehran

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Nahid zendehtbil

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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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