

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The effect of supervised exercise in the prevention of gestational diabetes mellitus in nulliparous women: A randomized control clinical trial

Protocol summary

Study aim

An Investigation of Sport Intervention in Pregnant Mothers in Pregnant Gestational Disease Prevention

Design

This is a randomized, parallel clinical trial study.

Settings and conduct

The study will be conducted in Damghan, Iran. Mothers at risk and with gestational diabetes will be detected based on clinical practice guidelines for screening, diagnosis, and treatment before and during pregnancy and after childbirth by Ministry of Health and Medical Education (2019); and having gestational diabetes will be finally approved by a gynecologist. Pregnant mothers introduced by specialist physicians from genealogy offices and clinics, and by midwifery staff at urban health centers will be evaluated by the main researcher in terms of inclusion criteria, nutritional status and physical activity level (by completing the international Pregnancy Physical Activity Questionnaire (PPAQ) and a Food Frequency Questionnaire (FFQ)).

Participants/Inclusion and exclusion criteria

Entrance: pregnant women who have normal fasting plasma glucose in their first pregnancy tests. Exit: one of the obstacles to not doing exercise in pregnancy.

Intervention groups

The intervention group will have an exercise intervention program for 8 sessions, 3 sessions per week, each lasting for 45 minutes, and the comparison group will have routine physical activity while receiving routine prenatal care.

Main outcome variables

Fasting plasma glucose

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141001019351N2**

Registration date: **2019-07-02, 1398/04/11**

Registration timing: **prospective**

Last update: **2019-07-02, 1398/04/11**

Update count: **0**

Registration date

2019-07-02, 1398/04/11

Registrant information

Name

Tayebe Zarezade

Name of organization / entity

Azad univercity of Damghan

Country

Iran (Islamic Republic of)

Phone

+98 23 2523 1711

Email address

tayebezarezade@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supervised exercise in the prevention of

gestational diabetes mellitus in nulliparous women: A randomized control clinical trial

Public title

Effect of exercise on preventing gestational diabetes

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

.Healthy pregnancy Normal Fasting plasma glucose in the first weeks of pregnancy Gestational age 18 to 20 weeks to start the plan Mother age 18 to 35 years old A resident of Damghan Control and care of pregnancy in the city of Damghan Contraindications without exercise in Pregnancy Adherence to the implementation of the plan

Exclusion criteria:

One of the obstacles to not doing exercise in pregnancy Mother's request to leave the plan at any time

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: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done after initial registration and obtaining informed consent. Random allocation will be done based on a list obtained from www.Randomization.com. After entering the required information, this website provides two lists of 40 people in two groups of intervention and comparison. At the end of each week, the project secretary will place subjects in the order of entry into the study in the intervention and comparison lists

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

This is a parallel randomized clinical trial.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

islamic azad university, semnan branch

Street address

islamic azad university, damghan branch

City

damghan

Province

Semnan

Postal code

36716 39998

Approval date

2018-12-06, 1397/09/15

Ethics committee reference number

IR.IAU.SEMNAN.REC.1398.002

Health conditions studied**1****Description of health condition studied**

Gestational diabetes melitus (GDM)

ICD-10 code

O00-O08

ICD-10 code description

Pregnancy with abortive outcome

Primary outcomes**1****Description**

FPG fasting plasma glucose

Timepoint

Week 7 to 10 and 24 to 28 weeks pregnant

Method of measurement

Fasting Blood Sampling

Secondary outcomes**1****Description**

OGTT(50Glocose)

Timepoint

24- 28 gestational age

Method of measurement

Blood test

2**Description**

Pregnant mother weighing

Timepoint

The first trimester of gestation, the second trimester of pregnancy, the third trimester of pregnancy, the termination of pregnancy

Method of measurement

Weighing scale for adults

3**Description**

Type of delivery

Timepoint

At birth

Method of measurement

The case is admitted to the pregnant mother's hospital

4**Description**

Baby weight

Timepoint

The first hour of birth

Method of measurement

Baby weighing scale

5**Description**

Baby's height

Timepoint

The first hour of birth

Method of measurement

Measuring meter

6**Description**

Round the head of the baby

Timepoint

The first hour of birth

Method of measurement

Measuring meter

7**Description**

Baby's chest

Timepoint

The first hour of birth

Method of measurement

Measuring meter

8**Description**

Apgar's first minute baby

Timepoint

The first minute of the baby's birth

Method of measurement

Apgar score for baby

9**Description**

Apgar's fifth minute baby

Timepoint

The fifth minute of the baby's birth

Method of measurement

Apgar score for baby

10**Description**

Duration of hospitalization

Timepoint

From hospital admission to discharge

Method of measurement

The case is admitted to the pregnant mother's hospital

11**Description**

Gestational age at the end of pregnancy

Timepoint

At birth

Method of measurement

Gestational age based on ultrasound 8 to 10 weeks based on CRL

12**Description**

Percent oxygen saturation

Timepoint

Minutes 1- 2 -3 -4 -5 -10

Method of measurement

Baby Oximeter pulse device

13**Description**

Duration of active phase of labor

Timepoint

When admitted to the hospital for termination of pregnancy

Method of measurement

Hospital file - Partograph form

14**Description**

Determining the rate of admission to the hospital after delivery

Timepoint

The first 24 hours of birth

Method of measurement

Newborn hospital records

15**Description**

The need for resuscitation measures in the baby

Timepoint

Baby birth

Method of measurement

Newborn hospital records

16**Description**

Childbirth injuries

Timepoint

The first 24 hours after birth

Method of measurement

Newborn hospital records

17**Description**

Maternal Maternal Injuries

Timepoint

The first 2 hours after childbirth
Method of measurement
Maternity hospital file

velayathos@semums.ac.ir
Web page address
<https://velayathos.semums.ac.ir/>

Intervention groups

1

Description

Intervention group: The intervention group program will be based on the principles of the design of the workout, by specifying the duration, severity, repetition, and type of exercise. The duration of the training in the first week is 60 minutes, in the second week, 100, and the third week, 150, and from the fourth week thereafter, 160 minutes. will be . Exercise intensity throughout the week with moderate intensity and based on the severity of talk test. Repeat the exercise in the first week, 4 times a week, the first two days, 10 minutes and 2 days later, 20 minutes, and from the second week, 5 days a week. Which will be divided according to the timing between days. Types of exercise in the first week, three times a week, once a practice of aerobics and Pilates, and from the second week to two days of walking and three days of aerobic and Pilates exercises during pregnancy. Aerobic exercises include a warming and cooling program and cardio exercises, and Pilates exercises are called seated xercise exercises.

Category

Prevention

2

Description

Control group: Control group can take physical activity while receiving usual care during pregnancy.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Private health clinics and specialized clinics and velayat hospital in Damghan

Full name of responsible person

tayebeh zarezadeh

Street address

Damghan velayat Hospital

City

Damghan

Province

Semnan

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3671637881

Phone

+98 23 3522 5124

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+98 23 3522 5129

Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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nnemati258@gmail.com

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<http://www.damghaniau.ac.ir/>

Grant name

does not have

Grant code / Reference number

ندارد

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Semnan University of Medical Sciences

Full name of responsible person

tayebeh zarezadeh

Position

phd student

Latest degree

Master

Other areas of specialty/work

Midwifery
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
tayebeh zarezadeh
Position
PHD student
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

Contact

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tayebeh zarezadeh
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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

IPD: Information and research data Ethic form: Complete the Ethic form by the patient

When the data will become available and for how long

IPD: 2019 Ethic form: 2019

To whom data/document is available

IPD: Researcher & Patient Ethic form: Patient

Under which criteria data/document could be used

IPD: Ethic form: Awareness of test results

From where data/document is obtainable

IPD: counseling and delivery service of the Avayetavalod

What processes are involved for a request to access data/document

IPD: Application form for the researcher and, if agreed, coordinated with the secretary of the design and attendance at the counseling and delivery service of the Avayetavalod

Comments