

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of the Individualized Education Program on the prevalence of gestational diabetes mellitus in pregnant by In Vitro Fertilization

Protocol summary

Summary

This study is a quasi-experimental study. The objective of the study is to evaluate The effect of the Individualized Education Program on the prevalence of gestational diabetes mellitus in pregnant by In Vitro Fertilization. Participants will include 170 pregnant women through In Vitro Fertilization (IVF). They will be divided into two groups (85 people in intervention group and 85 people in control group). Before the intervention, they will complete questionnaire of lifestyle for nutrition and eating habits, 24-hour dietary recall questionnaire for three days and Physical Activity Questionnaire by individuals in both groups. Height and weight will be measured and body mass index will be calculated. Samples will receive education about Diet, weight control, exercise and physical activity in 6 sessions in intervention group and controls will receive clinic Routine care. Participants of intervention and control groups will be checked by glucose tolerance test (GTT) at week 24 to 28 of pregnancy and again in 34 week for final diagnosis of gestational diabetes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020228847N2**

Registration date: **2017-04-12, 1396/01/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-12, 1396/01/23

Registrant information

Name

leila Neisani

Name of organization / entity

Iran University Medical of Science

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the Individualized Education Program on the prevalence of gestational diabetes mellitus in pregnant by In Vitro Fertilization

Public title

The effect of the Individualized Education Program on the prevalence of gestational diabetes mellitus in pregnant by In Vitro Fertilization

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Pre-pregnancy body mass index of 19 to 25; gestational age 12 to 16 weeks with LMP or ultrasound in the first trimester; In Vitro Fertilization is not due to PCOs factor; no history of diabetes in first-degree relatives (father, mother, sister, brother); no

history of previous neonatal mortality in pregnancy; no history of previous pregnancy with malformed infant or fetus; lack of macrosomia (birth weight more than 4000 grams); no history of gestational diabetes and preeclampsia in a previous pregnancy; No more than three times repeated abortions; the absence of chronic diseases (hypertension, cardiovascular disease, kidney disease, anemia, autoimmune); Lack of mental disease; Lack of education in the Department of Medical Sciences (Nursing, Nursing, Medical, Nutritional Science); normal FBS (less than 126) in the first quarter (of the case)

Exclusion criteria: smoking and drug abuse

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **170**

Randomization (investigator's opinion)

Not randomized

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

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran

City

Tehran

Postal code

Approval date

2017-01-23, 1395/11/04

Ethics committee reference number

IR.IUMS.REC 1395.9311373013

Health conditions studied

1

Description of health condition studied

Gestational Diabetes

ICD-10 code

O24

ICD-10 code description

Diabetes mellitus in pregnancy

Primary outcomes

1

Description

Gestational Diabetes

Timepoint

In 24-28 weeks and again in 34 week

Method of measurement

Screening test for gestational diabetes and GTT test

Secondary outcomes

empty

Intervention groups

1

Description

Education about Nutrition , weight control, physical activity during the sixth session since the arrival of up to 34 weeks of gestation for 15 to 20 minutes per session, coinciding with the visit of prenatal in intervention group

Category

Lifestyle

2

Description

routine care Of Clinics in control group

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Dr. Tehrani Nejad

Full name of responsible person

Leila Neisani

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Clinic of Dr. Ashrafi

Full name of responsible person

Leila Neisani
Street address
City
Tehran

3

Recruitment center

Name of recruitment center
Infertility clinic of Akbar Abadi Hospital
Full name of responsible person
Simin Jafari
Street address
Molavi Street
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4

Recruitment center

Name of recruitment center
Infertility clinic Of Firoozgar Hospital
Full name of responsible person
Street address
Karim Khan Street, Be Afarin Street
City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor of Research Of Nursing and Midwifery
Faculty of Iran University Of Medical Sciences
Full name of responsible person
Dr. Nahid Akbari
Street address
Nursing and Midwifery Faculty of Iran University Of
Medical Sciences, Rashid yasemi Street, Valiasr street
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor of Research Of Nursing and Midwifery
Faculty of Iran University Of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding *empty*

Person responsible for general inquiries

Contact

Name of organization / entity
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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty