

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Effect of coenzyme Q10 supplementation on glycemic index, lipid profile and inflammatory markers in women with gestational diabetes

Protocol summary

Study aim

Determination of the Effect of Co-Enzyme Q10 Supplementation on Glycemic Index, Lipid Profile, and Inflammatory Indicator in Gestational Gestational Patients in a Randomized Clinical Trial

Design

Clinical trials with control group, with parallel groups, blind, randomized. Random sequences will be generated using the Random Generator program.

Settings and conduct

This study is done at al-Zahra hospital in Shiraz. After identifying eligible people according to entry and exit criteria, in the first visit, the purpose and stages of the study are fully described to individuals, and if they so desire, they will be required to complete the written consent form. Subsequently, for each person, the general information form is completed. Patients will be assigned randomly into two groups of placebo and 200 mg coenzyme Q10 supplement. The duration of the intervention is also one month

Participants/Inclusion and exclusion criteria

inclusion criteria: Age between 18 and 40 years old Pregnant women whose blood glucose levels at 24-24 weeks of gestation have any of the following criteria based on the 2014 American Diabetes Association's 2014 guide, are considered as gestational diabetes: fasting plasma glucose (FPG) \geq 92 mg / dl; tolerance testing Oral glucose with 75 g glucose 1 hour (1-hOGTT) \geq 180 mg / dl; Oral glucose tolerance test 75 g Glucose 2 hours (2-hOGTT) \geq 153 mg / dl Individuals completing and delivering the informed consent form of the study. exclusion criteria: The sudden separation of the placenta from the fetus Premature rupture of amniotic sac Preeclampsia and eclampsia Hypo or hyperthyroidism History of any type of diabetes smoking Liver and kidney disease Taking antibiotics or glucocorticoids Treated with insulin.

Intervention groups

Control group: receiving placebo. Intervention group:

receiving Co Q10 supplementation.

Main outcome variables

Blood sugar level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080910001233N4**

Registration date: **2019-04-18, 1398/01/29**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-18, 1398/01/29**

Update count: **0**

Registration date

2019-04-18, 1398/01/29

Registrant information

Name

Maryam Asgharnia

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

asgharnia@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-17, 1398/01/28

Expected recruitment end date

2019-05-20, 1398/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of coenzyme Q10 supplementation on glycemic index, lipid profile and inflammatory markers in women with gestational diabetes

Public title

Effect of Coenzyme Q10 Supplementation on Gestational Diabetes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 and 40 years old fasting plasma glucose (FBS) \geq 92 mg / dl tolerance testing Oral glucose with 75 g glucose 1 hour (1-hOGTT) \geq 180 mg / dl Oral glucose tolerance test 75 g Glucose 2 hours (2-hOGTT) \geq 153 mg / dl Individuals completing and delivering the informed consent form of the study.

Exclusion criteria:

The sudden separation of the placenta from the fetus
Preeclampsia Eclampsia Hypothyroidism hyperthyroidism
History of any type of diabetes smoking Liver disease
kidney disease Taking antibiotics Taking glucocorticoids
Treated with insulin

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random sequences will be generated using the Random Generator program. Based on the random block method and considering the four blocks, 15 blocks will be generated for 60 patients. After generating the list, each person will be assigned a dedicated code and will be recognized by the person during the study with this code

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and researchers will be blinded by supplementation with the same package.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Guilan University of Medical Sciences

Street address

Research vice-chancellorship Building, in front of 17-Shahrivar Hospital, ShahidSiadati St., Namjoo Ave., Rasht, Guilan, IRAN

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2019-02-23, 1397/12/04

Ethics committee reference number

IR.GUMS.REC.1397.454

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

Gestational Diabetes

ICD-10 code

o24.4

ICD-10 code description

Gestational diabetes mellitus NOS

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

Blood sugar level

Timepoint

Before intervention, after intervention

Method of measurement

Colorimetric method

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

HDL-C

Timepoint

Before intervention, after intervention

Method of measurement

Colorimetric method

Intervention groups

1

Description

Intervention group: Intervention group: Take 200 milligrams of daily supplementation of coenzyme Q10

Category

Treatment - Other

2

Description

Control group: Placebo contains cellulose every day

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Dr.SeyedehHajarSharami

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Al-Zahra Hospital, Namjoo Ave., Rasht, Guilan, IRAN

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr.ShadmanNemati

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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

Rasht University of Medical Sciences

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

Rasht University of Medical Sciences

Full name of responsible person

Mohadeseh Aghayinejad

Position

Resident of Professor, Guilan university of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Position

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Latest degree

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Person responsible for updating data

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Sedighe Bab Eghbal

Position

MS of Health Education

Latest degree

Master

Other areas of specialty/work

Midwifery

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

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

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

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

Analytic Code

Undecided - It is not yet known if there will be 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

There is still planning to share and publish

When the data will become available and for how long

The beginning of the access period is 6 months after the publication of the study results.

To whom data/document is available

All interested in study

Under which criteria data/document could be used

Not yet planned for it.

From where data/document is obtainable

sharami@gums.ac.ir

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

Not yet planned for it.

Comments