Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 40 and 18 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) ≥ 92 mg / dl; tolerance testing Oral glucose with 75 g glucose 1 hour (1-hOGTT) ≥180 mg / dl; Oral glucose tolerance test 75 g Glucose 2 hours (2-hOGTT) ≥ 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)

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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 40 and 18 years old fasting plasma glucose (FBS) ≥ 92 mg / dl tolerance testing Oral glucose with 75 g glucose 1 hour (1-hOGTT) ≥180 mg / dl Oral glucose tolerance test 75 g Glucose 2 hours (2-hOGTT) ≥ 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
Street address
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
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Research vice-chancellorship Building, in front of 17-Shahrivar Hospital, ShahidSiadati St., Namjoo Ave., Rasht, Guilan, IRAN
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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
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Person responsible for updating data

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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