Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

Study of the effects of N-acetylcysteine administration on pregnancy outcomes and metabolic profiles in women with gestational diabetes mellitus

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of N-acetylcysteine administration on pregnancy outcomes and metabolic profiles in women with GDM.

Design

Study design: Randomized double-blind placebo-controlled trial. Patients will be assigned into two groups to receive N-acetyl cystein (n=38) or placebo (n=38).

Settings and conduct

Among patients with GDM referred to Shahid Beheshti gynecology and obstetrics Clinic affiliated to Kashan University of Medical Sciences, 76 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Drugs and placebos are similar. Fasting blood samples will be taken at baseline and 6 weeks after the intervention. At the beginning and the end of the intervention: 6 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with gestational diabetes aged 18 to 40 years. Exclusion criteria: Overt diabetes mellitus, taking any antioxidant agents 3 months before the intervention, needing insulin therapy, Hypo and hyperthyroidism, and Unwillingness to cooperate.

Intervention groups

IIntervention group: N-acetylcysteine 600 mg Tablet (Osve Pharmaceutical Co., Tehran, Iran), once a day, for 6 weeks orally. Control group: Placebo tablet (Osve Pharmaceutical Co., Tehran, Iran), once a day, for 6 weeks orally.

Main outcome variables

Outcomes: Insulin resistance (primary outcome) and lipid profiles, biomarkers of inflammation and oxidative stress, and pregnancy outcomes (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

The updating process was done before publishing the paper to correct the registration information.

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N71**
Registration date: **2020-04-21, 1399/02/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-16, 1399/10/27**
Update count: **1**

Registration date

2020-04-21, 1399/02/02

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-04, 1398/11/15

Expected recruitment end date

2020-08-05, 1399/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Study of the effects of N-acetylcysteine administration on pregnancy outcomes and metabolic profiles in women with gestational diabetes mellitus

Public title
Effects of N-acetylcysteine administration in treatment of women with gestational diabetes mellitus

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women with gestational diabetes mellitus. Individuals aged 18 to 40 years.
Exclusion criteria:
Overt diabetes mellitus Taking any antioxidant agents 3 months before the intervention Needing insulin therapy Hypo and hyperthyroidism Unwillingness to cooperate

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned into two groups. A randomization list will be generated from 1 to 76 by a random number generator (https://stattrek.com/statistics/random-number-generator.aspx) and patients were randomly assigned into each intervention group by their numbers. The block randomization technique with 1:1 ratio will be used to achieve balanced group sizes.

Blinding (investigator's opinion)
Double blinded

Blinding description
Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Shahid Beheshti Gynecology Clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of drugs. Drugs and placebos are in the same packaging at the Osve pharmaceutical company. Only the code is written on the packages. Patients and researcher will not know the type of drug. After analyzing the data, packet codes will be decoded. Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159

Approval date
2020-02-03, 1398/11/14

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1398.126

Health conditions studied

1

Description of health condition studied
Gestational diabetes mellitus

ICD-10 code
O24.9

ICD-10 code description
Unspecified diabetes mellitus in pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
Insulin resistance

Timepoint
At the beginning of the study and after 6 weeks of intervention

Method of measurement
Calculation using HOMA formula

Secondary outcomes

1

Description
Insulin

Timepoint
At the beginning of the study and after 6 weeks of

intervention

Method of measurement

Elisa kit

2

Description

Total cholesterol

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Enzymatic kit

3

Description

HDL

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Enzymatic kit

4

Description

Triglycerides

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Enzymatic kit

5

Description

Hs-CRP

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Elisa kit

6

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Spectrophotometry

7

Description

Glutathione

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Spectrophotometry

8

Description

Total antioxidant capacity

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Spectrophotometry

9

Description

Cesarean section rate

Timepoint

Delivery time

Method of measurement

checklist

10

Description

Preterm delivery

Timepoint

Delivery time

Method of measurement

checklist

11

Description

Polyhydramnios

Timepoint

End-of-trial

Method of measurement

Sonography

12

Description

Pre-eclampsia rate

Timepoint

During intervention

Method of measurement

checklist

13

Description

Macrosomia rate

Timepoint

Delivery time

Method of measurement

checklist

14

Description

Low birth weight

Timepoint

Delivery time

Method of measurement

checklist

15

Description
Newborns' hyperbilirubinemia
Timepoint
Delivery time
Method of measurement
checklist

16

Description
Newborns' hospitalization
Timepoint
Delivery time
Method of measurement
checklist

Intervention groups

1

Description
Intervention group: N-acetylcysteine 600 mg Tablet (Osve Pharmaceutical Co., Tehran, Iran), once a day, for 6 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo tablet (Osve Pharmaceutical Co., Tehran, Iran), once a day, for 6 weeks orally.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Gynecology and Obstetrics Clinic of Shahid Beheshti Hospital
Full name of responsible person
Dr. Zohreh Tabassi
Street address
Ghotbe Ravandi Boulevard, Kashan
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8115187159
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Hamidreza Banafsheh
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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
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Dr. Susan Assadpour
Position
Resident of gynecology and obstetrics
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Associate Professor

Latest degree

Specialist

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Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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