

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of thiamine supplementation on biomarkers of inflammation, oxidative stress and its related gene expression in patients with gestational diabetes

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of thiamine supplementation on inflammatory factors, oxidative stress biomarkers and its related gene expression in patients with gestational diabetes mellitus.

Design

Study design: Randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive thiamine supplement (n=30) or placebo (n=30).

Settings and conduct

Among patients with gestational diabetes referred to gynecology and obstetric Clinic affiliated to Kashan University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 6 weeks after the intervention. Intervention period: 6 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with gestational diabetes mellitus; aged 18 to 40 years. Exclusion criteria: taking any supplements before the intervention.

Intervention groups

Intervention group: 100 mg thiamine (Shafa Pharmaceutical Company, Karaj, Iran) daily for 6 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran), daily for 6 weeks orally.

Main outcome variables

Outcomes: hs-CRP (primary outcome) and oxidative stress biomarkers and its related gene expression (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: **IRCT20170513033941N58**

Registration date: **2019-05-24, 1398/03/03**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-06, 1399/03/17**

Update count: **1**

Registration date

2019-05-24, 1398/03/03

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-24, 1398/02/04

Expected recruitment end date

2019-05-25, 1398/03/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of thiamine supplementation on biomarkers of inflammation, oxidative stress and its related gene expression in patients with gestational diabetes

Public title

The effect of thiamine supplementation in the treatment of gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with gestational diabetes mellitus Individuals aged 18 to 40 years old

Exclusion criteria:

Overt diabetes mellitus Taking any supplements before the intervention 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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<25 and ≥ 25 kg/m²) and age (<30 and ≥ 30 y). Then, participants in each block will be randomly allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of computer software.

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 gynecology and obstetric clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of National Institute for Medical Research Development of Iran (NIMAD)

Street address

National Institute for Medical Research Development of Iran, Fatemi Avenue, Tehran

City

Tehran

Province

Isfahan

Postal code

1419693111

Approval date

2019-04-23, 1398/02/03

Ethics committee reference number

IR.NIMAD.REC.1398.035

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**

Hs-CRP

Timepoint

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

Method of measurement

Elisa kit

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

Nitric oxide

Timepoint

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

Method of measurement

Spectrophotometry

2**Description**

Malondialdehyde
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Spectrophotometry

3

Description
Glutathione
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Spectrophotometry

4

Description
Total antioxidant capacity
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Spectrophotometry

5

Description
Expressed levels of IL-1 gene
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
RT-PCR

6

Description
Expressed levels of TGF-beta gene
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
RT-PCR

7

Description
Expressed levels of VEGF gene
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
RT-PCR

8

Description
Expressed levels of TNF gene
Timepoint
At the beginning of the study and after 6 weeks of

intervention
Method of measurement
RT-PCR

Intervention groups

1

Description
Intervention group: 100 mg thiamine (Shafa Pharmaceutical Company, Karaj, Iran) daily for 6 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo (Barij Essence, Kashan, Iran), daily for 6 weeks orally.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Naghavi gynecology clinic
Full name of responsible person
Dr. Zohreh Tabassi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
National Institute for Medical Research Development of Iran (NIMAD)

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. Alireza Abed
Position
Assistant Professor
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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