

# 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

###### Name

Mohammadreza Sharif

###### Name of organization / entity

###### Country

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  $\geq 25$  kg/m<sup>2</sup>) and age (<30 and  $\geq 30$  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  
**Street address**  
Shahid Rajaei street, Kashan  
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## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
National Institute for Medical Research Development of Iran (NIMAD)  
**Full name of responsible person**  
Dr. Reza Malekzadeh  
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+98 21 6693 8037

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malek@tums.ac.ir

**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

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Medical Pharmacy

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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**  
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