

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of Calcium-D supplementation effects in sugar control in patients with gestational diabetes

Protocol summary

Study aim

Determine the effect of Calcium-D supplementation on sugar control of gestational diabetes

Design

A randomized, triple blind clinical trial, based on patients with gestational diabetes, which has two parallel groups.

Settings and conduct

Gestational diabetes is an important complication of pregnancy known as carbohydrate intolerance. Current treatments for gestational diabetes include a carbohydrate-based diet, some blood glucose lowering drugs and insulin therapy. In some studies, the effect of supplementation of calcium alone or in combination with vitamin D in the control and treatment of gestational diabetes has been mentioned. However, these results are contradictory in various studies and it is essential that the effect of this supplement on the control of gestational diabetes is determined. This study is a randomized controlled clinical trial that doing in Bahar Hospital of Shahroud. In this study patients, the person responsible for grouping patients and the person in charge of laboratory sampling and prescribing the medicine have been blinded

Participants/Inclusion and exclusion criteria

84 pregnant women suffering to gestational diabetes age limited 18-40 years old who have gestational age of 26 to 24 weeks; have GDM tests positive and have no history of previous glucose control, are included in the study.

Intervention groups

In the intervention group; Calcium-D was used to evaluate its efficacy in gestational diabetes, along with routine gestational diabetes therapy. In the control group; only routine gestational diabetes therapy has been used.

Main outcome variables

Measurement of blood glucose and glycosylated hemoglobin in the beginning of the study and three months after administration of Calcium-D

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100102002954N11**

Registration date: **2018-09-04, 1397/06/13**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-04, 1397/06/13**

Update count: **0**

Registration date

2018-09-04, 1397/06/13

Registrant information

Name

Mohammad Bagher Sohrabi

Name of organization / entity

Shahroud University of Medical Sciences and Health

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

mb.sohrabi@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Calcium-D supplementation effects in sugar control in patients with gestational diabetes

Public title

Calcium-D supplementation effects in sugar control in gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

GDM test positive in 26-24 weeks of pregnancy Pregnant women without the previous diagnosis of glucose intolerance Satisfaction in rasarach

Exclusion criteria:

Previous diabetes history Premature rupture of the membrane Pausing suddenly of corion Pregnancy hypertension Eclampsia Chronic hypertension Hypothyroidism Need to start insulin therapy during the intervention Dissatisfaction in rasarach

Age

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

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **84**

More than 1 sample in each individual

Number of samples in each individual: **4**

Blood glucose and hemoglobin glycosylated samples at the beginning of the study and three months after administration of Calcium-D

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: use block; Random unit: Individual; Randomization tool: Statistical software; Sequence Building: Using randomized 4 in 4 blocks; Hiding method: Use envelopes in the package

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, patients, project executives, and person responsible for measuring the sugar test and recording it are blinded. The division of patients into two groups A and B is done by a qualified nurse who has no knowledge of the actions performed in the two groups. Do experiments, drugs Prescribing and results recorder will be done by a qualified nurse without any knowledge of the type of medicine and patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahroud University of Medical Sciences

Street address

Research Deputy; Shahroud University of Medical Sciences; Haft Tir Square

City

Shahroud

Province

Semnan

Postal code

3614773947

Approval date

2017-05-24, 1396/03/03

Ethics committee reference number

IR.SHMU.REC.1396.41

Health conditions studied

1

Description of health condition studied

Gestational diabetes

ICD-10 code

O24.9

ICD-10 code description

Diabetes mellitus in pregnancy, unspecified

Primary outcomes

1

Description

Blood glucose measurement

Timepoint

At the beginning of the study and 3 months after starting Calcium-D intake

Method of measurement

Laboratory method of sugar measurement

2

Description

Measuring glycosylated hemoglobin

Timepoint

At the beginning of the study and 3 months after the start of Calcium-D intake

Method of measurement

Laboratory method for glycosylated hemoglobin measurement

Secondary outcomes

1

Description

Cratenin measurement

Timepoint

At the beginning of the study and 3 months after Calcium-D intake

Method of measurement

laboratory method of Cratenin measurement

2

Description

Urea measurement

Timepoint

At the beginning of the study and 3 months after Calcium-D intake

Method of measurement

laboratory method of urea measurement

Intervention groups

1

Description

Intervention group: for patients in the intervention group; administration of 500 mg of calcium carbonate per day plus 1000 units of vitamin D per day, together with routine gestational diabetes mellitus treatment during the study

Category

Treatment - Drugs

2

Description

Control group: for patients in the control group; only administration of routine gestational diabetes treatment during the study

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahar Hospital

Full name of responsible person

Dr. Mina Sadat Kohbodi

Street address

Bahar Hospital; 22 Bahman Street

City

Shahroud

Province

Semnan

Postal code

3619694668

Phone

+98 23 3224 7653

Fax

+98 23 3224 7653

Email

mina_kohbodi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hasan Emamian

Street address

Research deputy; Shahroud University of Medical Sciences; Haft Tir Square

City

Shahroud

Province

Semnan

Postal code

3614773947

Phone

+98 23 3239 4499

Fax

+98 23 3239 4800

Email

pajouhesh@shmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

The personal budget of researchers

Proportion provided by this source

90

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Bagher Sohrabi

Position

Educational Manager of Medical Faculty

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Faculty of Medicine, Shahroud University of Medical Sciences, Haft Tir Square

City

Shahroud

Province

Semnan

Postal code

3614773947

Phone

+98 23 3239 5054

Fax

+98 23 3239 4800

Email

mb.sohrabi@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahroud University of Medical Sciences

Full name of responsible person

Setare Ghanbari

Position

General Practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Imam Hossain Hospital; Imam Street

City

Shahroud

Province

Semnan

Postal code

3616651151

Phone

+98 23 3234 2000

Fax

+98 23 3233 3902

Email

setareh72ghanbari@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Shahroud University of Medical Sciences

Full name of responsible person

Setare Ghanbari

Position

General Practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Imam Hossain Hospital; Imam Street

City

Shahroud

Province

Semnan

Postal code

3616651511

Phone

+98 23 3234 2000

Fax

+98 23 3233 3902

Email

setareh72ghanbari@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available