

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Double blinded Clinical trial of comparison between the effect of ginger and placebo on blood glucose in the women with gestational diabetes in two groups of ginger and placebo

Protocol summary

Summary

Purpose of this 3rd phase research is investigating the effect of ginger tablets on the blood sugar of women with gestational diabetes whom they are in 24-28 weeks of pregnancy and are referred to Arash hospital. For these 80 pregnant women with gestational diabetes that are screened by glucose tolerance test will choose and divide into two groups and randomized through blocking. We will give ginger tablets in 3 tablets with dose 1500 milligrams to women in case group and placebo tablets to control group with same dose. Between two groups the blood sugar levels will test by using glucose tolerance test values and homeostasis model assessment index before and 6 weeks after the intervention. In addition non of researchers and research instances do not know any of groups uses the ginger tablets or placebos.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090523897N1**

Registration date: **2016-05-10, 1395/02/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-10, 1395/02/21

Registrant information

Name

Dr. Shahideh Jahanian Sadatmahalleh

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 4826

Email address

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Recruitment status

Recruitment complete

Funding source

Tarbiat Modares University

Expected recruitment start date

2016-01-10, 1394/10/20

Expected recruitment end date

2016-05-10, 1395/02/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double blinded Clinical trial of comparison between the effect of ginger and placebo on blood glucose in the women with gestational diabetes in two groups of ginger and placebo

Public title

Ginger Tablets effect on gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women with one fetus in uterine; The women who their Fasting Blood Sugars are below of 92 in their first visit of prenatal care; The women with gestational diabetes diagnosis in 24-28 weeks of pregnancy; Lack of using drugs that affects blood sugar; Lack of having underlying disease such as cardiovascular, respiratory or renal diseases; The women

who had normal Blood Sugar before pregnancy; Lack of hard exercise; Lack of need to insulin therapy by doctor diagnose; Women who candidate for low sugar diet treatment; exclusion criteria: any reaction of body and sensitivity to tablets

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Randomization: In this research randomization is done through 3 and 6 blocks and through this blocks persons go to drug group or placebo group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tarbiat Modares University

Street address

Tarbiat Modares University, Nasr bridg, Ale ahmad high way, Tehran

City

Tehran

Postal code

14115-331

Approval date

2015-12-19, 1394/09/28

Ethics committee reference number

IR.TMU.REC.1394.181

Health conditions studied

1

Description of health condition studied

Gestational diabetes

ICD-10 code

O24.4

ICD-10 code description

Diabetes mellitus arising in pregnancy

Primary outcomes

1

Description

Blood glucose

Timepoint

Before intervention, Six weeks after intervention

Method of measurement

Glucose Tolerance Test. In this test fast blood sugar of persons will measure and then 1 hour and 2 hours after using 75 gr glucose blood sugar of them will measure.

2

Description

Resistance to insulin index

Timepoint

Before intervention, Six weeks after intervention

Method of measurement

Through measure of fast blood sugar and fasting insulin with formula

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group will take ginger tablets which made by dineh company and contain 500 milligram of ginger, they will use 1500 milligram daily for 6 weeks.

Category

Treatment - Drugs

2

Description

Control groups take placebo tablets in dose 500 milligrams which are made by Dineh company and use 1500 milligrams of these placebos daily for 6 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash hospital

Full name of responsible person

Shahide Jahanian

Street address

Arash hospital, third Sq. of Tehranpars, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tarbiat Modares University

Full name of responsible person

Mansoure Movahedin

Street address

Faculty of Medical Science 1 , Tarbiat Modares University , Nasr bridge, Jalal Al Ahmad Highway,Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Tarbiat Modares University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Shahideh Jahanian

Position

Assistant professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Shahideh Jahanian

Position

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Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty