

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Ginger Capsule on Blood Sugar Control status in Gestational Diabetes: a Triple Blind Randomized Controlled Trial

Protocol summary

Summary

The current study is a randomized, triple-blind, placebo-controlled trial. Research setting will be high risk pregnancy clinics of Taleghany and Alzahra hospitals in Tabriz. This clinical trial will be conducted on 76 pregnant women. Eligible people after obtaining written informed consent qualified subject to a randomized block design with four and six blocks and with allocation ratio of 1:1 would be allocated in two group. 500 mg capsules of ginger and placebo with similar appearance will be prepared by a pharmacist. The placebo capsules in order to scent after preparing, will be placed in the vicinity of ginger powder for two weeks and then will be packaged in similar cans. This drug is administered (daily, every 12 hours one capsule) from 28 weeks of gestation for 8 weeks. The primary outcomes of this study will be Fasting blood sugar control status for women with gestational diabetes and intake dose of insulin , secondary outcomes will be prevalence of preeclampsia, urinary tract infections, Mean of HbA1C, Fetal bio metric criteria, the number of mothers visits by a specialist physician, side events and satisfaction of drug using during the study . After collecting all the information, the data will be analyzed by using descriptive and analytical statistics of SPSS 21 software including ANCOVA and repeated measure ANOVA test; all of the analyzes will be conducted on the basis of Intention to treat analysis.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT201604043027N36**

Registration date: **2016-12-08, 1395/09/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-08, 1395/09/18

Registrant information

Name

Fahimeh Sehhatie Shafaie

Name of organization / entity

Tabriz university of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 1479 6770

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sehhatief@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Vice-Chancellor of Tabriz University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Ginger Capsule on Blood Sugar Control status in Gestational Diabetes: a Triple Blind Randomized Controlled Trial

Public title

The Effect of Ginger Capsule on Blood Sugar Control Status in Women with Gestational Diabetes

Purpose

Treatment

IR.TBZMED.REC.1395.103

Inclusion/Exclusion criteria

Inclusion criteria: Having an ultrasound based on singleton pregnancy; Gestational age between 24-28 weeks; Pregnant women aged 18-35 years; Pregnant woman with gestational diabetes who inject insulin and respond to insulin treatment; Normal blood pressure (less than 140/90 mmHg) in the current pregnancy and the absence of proteinuria in pregnancy tests; have at least read and write literacy; Willingness to participate in the study; Having telephone number and address for follow up; Having health records in Taleghani and ALzahra hospitals in Tabriz. Exclusion criteria: Alcohol or tobacco consumption; The use of traditional medicines, especially cinnamon; Mothers with a history of chronic hypertension; Blood glucose less than 70 mg/dl

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Research Vice-Chancellor, number 2 Central Building, Tabriz University of Medical Sciences, Golgasht ave, Tabriz, Iran

City

Tabriz

Postal code

5165665931

Approval date

2016-05-10, 1395/02/21

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

GDM

ICD-10 code

E00-E90

ICD-10 code description

endocrine, nutritional and metabolic diseases

Primary outcomes

1

Description

Fasting blood sugar before and after of intervention in groups of study

Timepoint

Before intervention 2, 4, 6 and 8 weeks after intervention

Method of measurement

Laboratory and check list

2

Description

Average blood sugar 2 hours after meals before and after intervention in groups of study

Timepoint

Before intervention 2, 4, 6 and 8 weeks after intervention

Method of measurement

Laboratory and check lists

3

Description

Insulin dose in the study groups

Timepoint

8 weeks after intervention

Method of measurement

check lists

Secondary outcomes

1

Description

Incidence of urinary tract infection in the study groups

Timepoint

8 weeks after intervention

Method of measurement

Laboratory and check list

2

Description

The mean of HbA1C in the study groups

Timepoint

8 weeks after intervention

Method of measurement

Laboratory and check list

3

Description

The fetal biometric criterias (femur length, head circumference, biparietal diameter, abdominal circumference and fetal weight) in the study groups

Timepoint

8 weeks after intervention

Method of measurement

Sonography and check list

4

Description

Incidence of preeclampsia in the study groups

Timepoint

8 weeks after intervention

Method of measurement

The blood pressure according to millimeter of mercury by using an analog sphygmomanometer and random urine albumin by using diagnostic strips for urine protein assay

5

Description

Mothers satisfaction of the received drugs in the study groups

Timepoint

8 weeks after intervention

Method of measurement

The check list of satisfaction of received drug

6

Description

Frequency of side events in the study groups

Timepoint

8 weeks after intervention

Method of measurement

The side events check list

7

Description

Number of specialist physician visits to control diabetes in study groups

Timepoint

8 weeks after intervention

Method of measurement

check list

Intervention groups

1

Description

Intervention group: Ginger capsule, 500 mg, orally, daily (one capsule every 12 hours) for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: placebo, orally, quite similar to ginger capsule, daily (one capsule every 12 hours) for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani and Alzahra hospitals in Tabriz

Full name of responsible person

Bahramian, Zohre

Street address

Faculty of nursing and midwifery

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Mirghafourvand

Street address

Research Vice-Chancellor, number 2 Central Building, Tabriz University of Medical Sciences, Golgasht ave, Tabriz, Iran

City

Tabriz

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Tabriz University of Medical Sciences

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

Faculty of nursing and midwifery

Full name of responsible person

Shafaie sehhatie fahimeh

Position

Master of midwifery

Other areas of specialty/work

Street address

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Person responsible for updating data

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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