

# 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)

###### Phone

+98 41 1479 6770

###### Email address

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**

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## Person responsible for scientific inquiries

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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*