# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The Effect of Oral Capsule of hydro-alcoholic Extract of Red Onion (Allium cepa) on Blood Glucose in Women with Gestational diabetes mellitus under Diet Therapy

## Protocol summary

**Study aim**
The Effect of Oral Capsule of hydro-alcoholic Extract of Red Onion (Allium cepa) on Blood Glucose in women with Gestational diabetes mellitus under Diet Therapy

**Design**
Phase 3 clinical trial with placebo group, A randomized, three -blind, parallel group of 82 pregnant women with gestational diabetes mellitus was selected as available.

**Settings and conduct**
Research units for women with gestational diabetes will be eligible to be referred to health centers in Mashhad. At the beginning of the study, and at the end of the second and fourth weeks, fasting blood glucose testing and two hours after a meal will be performed.

**Participants/Inclusion and exclusion criteria**
Conditions of entry: Persian and resident of Mashhad, maternal age between 35-18 years, single pregnancy, gestational age 30-24 weeks, gestational diabetes confirmed by tests and physicians, fasting blood sugar following 93 mg/dl and blood sugar two hours after meals below 120 mg/dl, serum glucose level fasting below 92 mg/dl L in the first pregnancy visit. Non-entry conditions: lack of medical condition and midwifery problems, under the view of psychiatrists in the last 6 months and non-use of mental drugs, lack of sensitivity to onion or lyliase family, abnormal results of screening of abnormalities and sonography of fetal anomaly.

**Intervention groups**
The intervention group received oral capsules containing 500 mg of red onion extract and the placebo group received capsules containing 500 mg avicel twice daily for 4 weeks.

**Main outcome variables**
Fasting blood glucose and two hours after meals

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20200224046607N1**
Registration date: **2020-03-29, 1399/01/10**
Registration timing: **prospective**

Last update: **2020-03-29, 1399/01/10**
Update count: **0**

**Registration date**
2020-03-29, 1399/01/10

**Registrant information**

**Name**
Farzaneh Salajegheh

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 51 3859 1511

**Email address**
salajeghehtf971@mums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-04-20, 1399/02/01

**Expected recruitment end date**
2020-10-22, 1399/08/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The Effect of Oral Capsule of hydro-alcoholic Extract of Red Onion (Allium cepa) on Blood Glucose in Women with Gestational diabetes mellitus under Diet Therapy

**Public title**
"Red Onion in Gestational diabetes mellitus"

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Iranian nationality and resident in Mashhad Has minimum literacy skills Written consent to participate in the study Phone number for urgent contact with yourself or family members Pregnant mother age between 18-35 years Single pregnancy Gestational age 30-24 weeks Gestational diabetes is confirmed by tests and a doctor Fasting blood glucose test and two hours postprandial (to confirm treatment of gestational diabetes with post-OGTT impairment) fasting blood glucose below 93 mg / dl and two hours postprandial blood glucose below 120 mg / dl and confirmation of gestational diabetes control With a diet by a gynecologist Fasting serum glucose levels below 92mg / dl at first pregnancy visit Normal outcome of fetal malformation screening tests and fetal anomaly ultrasound

**Exclusion criteria:**
Addiction to psychotropic substances, stimulants, alcohol, tobacco and opioids Having a medical condition Having midwifery problems Being a psychiatrist in the last 6 months and taking psychotropic drugs Allergy to onions or Lilias family members Preventive Speech and Behavioral Disorders Communication with Researcher

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

**Gender**
Female

**Phase**
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **82**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Sampling was done using available sampling and random allocation through binary blocks created by random Allocation Software, using random number table www.randomization.com in two groups (intervention and control).In fact, randomization is performed using binary blocks AB(1) and BA(2), so that A is the intervention group and B is the placebo group. The method of concealment would be to provide sealed envelopes.

**Blinding (investigator's opinion)**
Triple blinded

**Blinding description**
In order to blind the capsule of red onion extract and placebo, the researcher is provided with similar shapes and cans. Each box contains a code that the pharmacy consulting professor is aware of. Individuals with inclusion criteria are grouped according to the codes using a random number table. Therefore, by the end of the study, the researcher and the statistical analyst will not be aware of the codes for the red onion and placebo extract capsules.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Mashhad University of Medical Sciences-School of Nursing and Midwifery

**Street address**
School of Nursing and Midwifery, Ibn Sina Street, mashhad university of medical sciences, iran

**City**
Mashhad

**Province**
Razavi Khorasan

**Postal code**
9137913199

**Approval date**
2020-02-18, 1398/11/29

**Ethics committee reference number**
IR.MUMS.NURSE.REC.1398.104

## Health conditions studied

### 1

**Description of health condition studied**
Gestational Diabetes Mellitus

**ICD-10 code**
O24.4

**ICD-10 code description**
Diabetes mellitus arising in pregnancy

## Primary outcomes

### 1

**Description**
Fasting blood glucose

**Timepoint**
At baseline, 2 weeks and 4 weeks after intervention

**Method of measurement**
Intravenous Blood Test

**2**

**Description**
Blood glucose two hours after meals
**Timepoint**
At baseline, 2 weeks and 4 weeks after intervention
**Method of measurement**
Intravenous Blood Test

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Take the red onion extract capsule twice daily and in a 500 mg capsule half an hour after breakfast and lunch, with a 6 to 7 hour interval between meals and routine care including routine gestational diabetes training For 4 weeks.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: Take Avesil containing placebo (microcrystalline cellulose) capsules two times a day, and a 500-mg capsule half an hour after breakfast and lunch, with a 6 to 7-hour interval between meals and routine care including diet training The usual diet will get gestational diabetes for 4 weeks.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Health Center No. 2 (Mofateh, Vahdat, Imam Hassan, Amir al-Momenin centers)
**Full name of responsible person**
Ali Asghar Mahmoudi
**Street address**
next to Vahdat park, Vahdat street, Five ways Down the street
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
۹۱۵۳۹۱۳۱۵۳
**Phone**
+98 51 3368 3000
**Email**
M2HCenter@mums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Dr. Mohsen Tafaghodi
**Street address**
School of Nursing and Midwifery, Ibn Sina Street, mashhad university of medical sciences, iran
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9137913199
**Phone**
+98 51 3859 1511
**Fax**
+98 51 3859 7313
**Email**
tafaghodim@mums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Mashhad University of Medical Sciences
**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**
Mashhad University of Medical Sciences
**Full name of responsible person**
Farzaneh salajegheh
**Position**
student
**Latest degree**
Bachelor
**Other areas of specialty/work**
Midwifery
**Street address**
School of Nursing and Midwifery, Ibn Sina Street, mashhad university of medical sciences, iran
**City**
Mashhad
**Province**

Razavi Khorasan

**Postal code**
9137913199

**Phone**
+98 51 3859 1511

**Fax**
+98 51 3859 7313

**Email**
salajeghehtf971@mums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Mashhad University of Medical Sciences

**Full name of responsible person**
Raheleh Babazadeh

**Position**
Assistant Professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Midwifery

**Street address**
School of Nursing and Midwifery, Ibn Sina Street, mashhad university of medical sciences, iran

**City**
Mashhad

**Province**
Razavi Khorasan

**Postal code**
9137913199

**Phone**
+98 51 3859 1511

**Fax**
+98 51 3859 7313

**Email**
BabazadehR@mums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Mashhad University of Medical Sciences

**Full name of responsible person**
Farzaneh Salajegheh tezerji

**Position**
student

**Latest degree**
Bachelor

**Other areas of specialty/work**
Midwifery

**Street address**
School of Nursing and Midwifery, Ibn Sina Street, mashhad university of medical sciences, iran

**City**
Mashhad

**Province**
Razavi Khorasan

**Postal code**
9137913199

**Phone**
+98 51 3859 1511

**Fax**
+98 51 3859 7313

**Email**
salajeghehtf971@mums.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available

**Study Protocol**
Yes - There is a plan to make this available

**Statistical Analysis Plan**
Yes - There is a plan to make this available

**Informed Consent Form**
Yes - There is a plan to make this available

**Clinical Study Report**
Yes - There is a plan to make this available

**Analytic Code**
Yes - There is a plan to make this available

**Data Dictionary**
Yes - There is a plan to make this available

**Title and more details about the data/document**
Documents are shared after they are unrecognizable.

**When the data will become available and for how long**
8 months after recording the results

**To whom data/document is available**
All researchers

**Under which criteria data/document could be used**
All mothers with gestational diabetes and midwifery staff

**From where data/document is obtainable**
Email to address salajeghehtf971@mums.ac.ir

**What processes are involved for a request to access data/document**
Initially, an e-mail will be sent to the library of Mashhad School of Nursing and Midwifery, if not answered for up to one week.

**Comments**