

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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 Liliac 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

9153913153

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

Rahelah 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