Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of Ramadan fasting on the clinical and laboratory factors of type 2 diabetic patients treated with Insulin or Insulin secretory drugs by means of Continuous Glucose Monitoring (CGM)

Protocol summary

Study aim

Determining the effect of fasting during Ramadan on clinical and laboratory factors in type 2 diabetic patients treated with insulin or insulin secretagogues

Design

A non-randomized clinical trial without control group and without blinding, involving 21 patients.

Settings and conduct

Patients visiting the adult endocrinologist's office in Mashhad prior to the start of Ramadan who wish to fast during the month will be enrolled in the study. Participants will fast under medical supervision, and their blood glucose fluctuations during the fast will be measured and recorded over a 14-day period. There is no blinding in this study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Diagnosis of type 2 diabetes 2. Age of 18 to 65 years 3. Access to a smartphone capable of running the application associated with the CGM device 4. Under treatment with Insulin or Insulin secretagogues 5. Willingness to fast for at least 14 days during Ramadan 6. Successful experience fasting in previous years Exclusion Criteria: 1. Change in the patient's risk score resulting in classification within the "contraindicated for fasting" group 2. Discontinuation of fasting by the patient 3. Patient's withdrawal of consent to continue participating in the study

Intervention groups

This study involves only one intervention group with no control group. The only intervention will be fasting during Ramadan, which will be undertaken based on the patients' own preference. Fluctuations in the participants' blood glucose levels will be recorded throughout the 14 days of fasting.

Main outcome variables

Blood sugar fluctuations during fasting and two months after the end of fasting by CGM, Changes in insulin dose and timing during fasting, Weight, Systolic and diastolic blood pressure, Average fasting blood sugar, Average postprandial blood sugar, HBA1C, Triglycerides, Cholesterol, LDL, HDL, Creatinine, GFR

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260429069208N1**
Registration date: **2026-09-26, 1405/07/04**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-26, 1405/07/04**
Update count: **0**

Registration date

2026-09-26, 1405/07/04

Registrant information

Name

Samaneh Abolbashari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3881 2643

Email address

abolbasharism@mums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

Expected recruitment end date

2027-02-19, 1405/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Ramadan fasting on the clinical and laboratory factors of type 2 diabetic patients treated with Insulin or Insulin secretory drugs by means of Continuous Glucose Monitoring (CGM)

Public title

The effect of Ramadan fasting on diabetic patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Type 2 diabetes Age: 18 to 65 years Access to a smartphone that can be used to install the software related to the CGM device Under treatment with insulin or insulin secretagogues Intention to fast for at least 14 days during Ramadan Successful fasting experience in previous years

Exclusion criteria:

Change in patient's risk score and placement in the fasting prohibition group Discontinuing of fasting Patient not consenting to continue participating in the study

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **21**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences Ethics committee

Street address

Vice-Presidency for Research and Technology, 4th Floor, Dr. Shahid Khwarazmi Educational Complex, University Campus, Eastern Gate of Ferdowsi University of Mashhad, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2025-10-07, 1404/07/15

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1404.398

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11.9

ICD-10 code description

Type 2 diabetes mellitus without complications

Primary outcomes

1

Description

Fluctuations of Blood Glucose

Timepoint

Checking Blood Glucose fluctuations every 15 minutes for 14 days during fasting in Ramadan and then for 14 days, two months after the end of Ramadan.

Method of measurement

The amount of Glucose in the interstitial fluid is measured and recorded by a CGM device.

Secondary outcomes

1

Description

Weight

Timepoint

During fasting and 2 months after the end of Ramadan

Method of measurement

Beurer Glass Scale, GS 206

2

Description

Blood pressure

Timepoint

During fasting and 2 months after the end of Ramadan

Method of measurement

Blood pressure gauge

3

Description
Average fasting blood sugar
Timepoint
During fasting and 2 months after the end of Ramadan
Method of measurement
Continuous Glucose Monitoring (CGM) device

Intervention groups

1

Description
Intervention group: This study involves a single intervention group. Participants in this group will voluntarily fast during the month of Ramadan. No other intervention will be administered. Blood glucose fluctuations will be measured and recorded over a 14-day period using a Continuous Glucose Monitoring (CGM) device. We will use the Sibionics CGM device, purchased from Farir Asa Teb Company.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Adult Endocrinologist's Office
Full name of responsible person
Zahra Mazloum Khorasani
Street address
Abshar building, Moallem Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9178656553
Phone
+98 915 109 8005
Email
mazloumz@mums.ac.ir
Web page address
https://dr-mazloumkh.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
Vice-Presidency for Research and Technology, 4th Floor, Dr. Shahid Khwarazmi Educational Complex, University Campus, Eastern Gate of Ferdowsi University of Mashhad, Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3142 8801
Email
ramresearch@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
Samaneh Abolbashari
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Molecular Medicine
Street address
Department of Internal Medicine, Second Floor, Ghaem Hospital, Ahmad Abad Boulvard
City
Mashhad
Province
Razavi Khorasan
Postal code
99199-91766
Phone
+98 915 118 7681
Email
abolbasharism@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person
Zahra Mazloim Khorasani

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Endocrinologist

Street address
Department of Internal Medicine, Second Floor, Ghaem Hospital, AhmadAbad Boulvard

City
Mashhad

Province
Razavi Khorasan

Postal code
99199-91766

Phone
+98 915 109 8005

Email
mazloumz@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Samaneh Abolbashari

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Molecular Medicine

Street address
Ghaem Hospital

City
Mashhad

Province
Razavi Khorasan

Postal code
99199-91766

Phone
+98 51 3881 2643

Email
abolbasharism@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The project proposal, the results of the data analysis, and the informed consent form, if necessary, will be available for sharing with other researchers.

When the data will become available and for how long
From March 2027

To whom data/document is available
People working in academic institutions

Under which criteria data/document could be used
N/A.

From where data/document is obtainable
By sending email to abolbasharism@mums.ac.ir

What processes are involved for a request to access data/document
The data will be sent via email upon approval by the principal investigator.

Comments