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Glimepiride versus gliclazide modified-release in type 2 diabetes patients fasting during Ramadan in Iraq

Submission date
04/03/2026

Recruitment status
No longer recruiting

Registration date
06/03/2026

Overall study status
Completed

Last Edited
06/03/2026

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Millions of Muslims with Type 2 diabetes fast during the holy month of Ramadan each year, which changes meal timing and can cause dangerous swings in blood sugar levels. Doctors need clear evidence about which diabetes medicines are safest and most effective to use during this period. This study compared two commonly prescribed diabetes tablets — glimepiride and gliclazide modified-release (MR) — to determine which provides better blood sugar control and safety for patients with Type 2 diabetes fasting during Ramadan in Iraq, where such comparative data were previously lacking.

Who can participate?
Adults aged 18 to 65 years with a confirmed diagnosis of Type 2 diabetes for at least 1 year, already prescribed either glimepiride 2 mg once daily or gliclazide modified-release 60 mg once daily on a stable regimen for at least 8 weeks, who intended to fast during Ramadan 2023

What does the study involve?
About 6 weeks before Ramadan, all patients attended a baseline clinic visit where blood tests were taken (including HbA1c and a full cholesterol panel) and they received structured education on how to monitor their own blood sugar four times a day (before the pre-dawn meal, at midday, in the late afternoon, and 2 hours after breaking the fast), when to break their fast if blood sugar became dangerously high (above 300 mg/dL) or low (below 70 mg/dl), how to plan meals and fluid intake during fasting hours, and how to recognise symptoms of low and high blood sugar. During the 29 to 30 days of Ramadan, patients recorded all daily blood sugar readings in a structured diary and received weekly telephone check-in calls from the clinical team. No medicines were changed during the study. A final clinic visit with repeat blood tests took place within 1 week after Ramadan ended.

What are the possible benefits and risks of participating?
Potential benefits included closer monitoring of blood sugar throughout Ramadan, personalised guidance on fasting safety, and contribution to evidence that will help future patients with diabetes make safer choices during Ramadan. The main risks were low blood sugar

(hypoglycaemia, below 70 mg/dl) and high blood sugar (hyperglycaemia, above 300 mg/dl) associated with prolonged daily fasting, both of which were actively mitigated by structured pre-Ramadan education, four-times-daily self-monitoring, clear fast-breaking thresholds, and weekly telephone support from the clinical team. No severe hypoglycaemic episodes requiring emergency care occurred in either treatment group.

Where is the study run from?
Thi-Qar Specialized Diabetes, Endocrine, and Metabolism Center (TDEMC) (Iraq)

When is the study starting and how long is it expected to run for?
February 2023 to April 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Adel Gassab Mohammed, adelgassab@utq.edu.iq

Contact information

Type(s)
Scientific, Principal investigator, Public

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Additional identifiers

Study information

Scientific Title
Sulfonylureas during Ramadan in Iraqi type 2 diabetes patients

Study objectives
To compare the change in glycated haemoglobin (HbA1c, %) from baseline to post-Ramadan between patients with Type 2 diabetes mellitus treated with glimepiride 2 mg once daily versus gliclazide modified-release 60 mg once daily during Ramadan 2023.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 04/01/2023, Institutional Research Ethics Committee (IREC), Thi-Qar College of Medicine, University of Thi-Qar (Nasiriyah, ThiQar, 64001, Iraq; +964 (0)781 945 6580; medicine-college@utq.edu.iq), ref: 49114

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Diagnostic, Screening, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus (T2DM) in the context of Ramadan fasting

Interventions
Participants in both groups received their pre-existing, physician-prescribed oral sulfonylurea therapy unchanged throughout the study period: glimepiride 2 mg once daily (n = 67) or gliclazide modified-release 60 mg once daily (n = 77), both administered orally with the pre-dawn meal (Suhoor) during Ramadan. No investigator-initiated treatment changes, dose titration, or switching were performed. All participants additionally received a structured pre-Ramadan education programme at the baseline visit covering self-monitoring of blood glucose technique (four readings daily), mandatory fast-breaking glucose thresholds (<70 mg/dL or > 300 mg/dL), dietary and hydration guidance, and symptom recognition, supplemented by weekly standardised telephone follow-up calls from the clinical team throughout Ramadan.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Glimepiride, gliclazide modified-release (MR)

Primary outcome(s)
1. Glycated haemoglobin (HbA1c, %) measured using venous blood sample analysed at a certified laboratory using high-performance liquid chromatography (HPLC) or immunoturbidimetry at baseline (6 weeks before Ramadan) and within 1 week after Eid al-Fitr

Key secondary outcome(s)

Completion date
01/04/2023

Eligibility

Key inclusion criteria
1. Adults aged 18–65 years
2. Confirmed diagnosis of Type 2 diabetes mellitus of at least 1 year duration
3. Currently prescribed glimepiride 2 mg once daily or gliclazide modified-release 60 mg once daily on a stable regimen for a minimum of 8 weeks
4. Intending to fast during Ramadan 2023
5. Classified as intermediate risk per International Diabetes Federation-Diabetes and Ramadan Alliance (IDF-DAR) 2021 Practical Guidelines
6. Able and willing to perform self-monitoring of blood glucose four times daily and attend clinic visits

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
144

Key exclusion criteria
1. Type 1 diabetes mellitus
2. Current use of insulin or GLP-1 receptor agonist therapy; pregnancy or planned pregnancy
3. Severe hepatic dysfunction; severe renal dysfunction (eGFR <30 ml/min/1.73 m^2)
4. Recent cardiovascular events within the preceding six months
5. Classification as high risk per IDF-DAR 2021 Practical Guidelines
6. Inability or unwillingness to perform self-monitoring of blood glucose
7. Any condition deemed by the treating physician to make fasting medically unsafe

Date of first enrolment
01/02/2023

Date of final enrolment

01/03/2023

Locations

Countries of recruitment
Iraq

Sponsor information

Organisation
Thi Qar University

ROR
https://ror.org/02ypa8k59

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available