Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of Blood Glucose Control and Associated Outcomes Using a Targeted Pharmacotherapy Protocol Compared to Current Protocol in Adult Liver Transplant: Non-parallel, Non-randomized Clinical Trial

Protocol summary

Study aim

Evaluation the effect of a targeted pharmacotherapy protocol based on patient conditions on improving the blood glucose control and associated outcomes in liver transplantation

Design

First, patients in the control group (pre protocol) will be evaluated and the sample size of this group will be completed, and then, after the targeted pharmacotherapy protocol is developed, patients in the intervention group (protocol) will be treated and evaluated based on the pharmacotherapy protocol.

Settings and conduct

This study is a non-parallel, non-randomized clinical trial. Eligible patients will be selected from among liver transplant recipients at Imam Khomeini Hospital complex in Tehran. After obtaining informed consent, patients will be included in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Liver transplant recipients aged 18 to 65 years Deceased donor liver transplant Blood glucose level higher than 140 mg/dL intraoperatively/postoperatively (with or without a history of diabetes) Exclusion criteria: Recent surgery within 30 days before the transplant Multi-organ transplant recipients Participate in other interventional clinical trials simultaneously

Intervention groups

Control group (pre protocol): Blood glucose control will be performed according to the current protocol. Intervention group (protocol): Blood glucose control will be performed according to a targeted pharmacotherapy protocol based on the patient's condition.

Main outcome variables

Average blood glucose level - Time to reach target blood glucose level (so that it is in the target range for 3 consecutive times) - Number of hyperglycemic and hypoglycemic episodes - Amount of change in blood glucose reduction in the first 48 hours after transplantation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241025063493N1**
Registration date: **2025-01-03, 1403/10/14**
Registration timing: **registered_while_recruiting**

Last update: **2025-01-03, 1403/10/14**
Update count: **0**

Registration date

2025-01-03, 1403/10/14

Registrant information

Name

Yekta Rameshi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-22, 1403/08/01

Expected recruitment end date

2025-10-23, 1404/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Blood Glucose Control and Associated Outcomes Using a Targeted Pharmacotherapy Protocol Compared to Current Protocol in Adult Liver Transplant: Non-parallel, Non-randomized Clinical Trial

Public title
Blood Glucose Control with a Targeted Pharmacotherapy Protocol in Liver Transplant Recipients
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Liver transplant recipients aged 18 to 65 years Deceased donor liver transplant Blood glucose level higher than 140 mg/dL intraoperatively/postoperatively (with or without a history of diabetes)
Exclusion criteria:
Recent surgery within the past 30 days before the transplant Multi-organ transplant recipients Participate in other interventional clinical trials simultaneously
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **134**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of The Institute of Pharmaceutical Sciences -Tehran University of Medical
Street address
Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1417614411
Approval date
2024-10-19, 1403/07/28
Ethics committee reference number
IR.TUMS.TIPS.REC.1403.132

Health conditions studied

1

Description of health condition studied
Peri-liver transplant hyperglycemia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Comparison of blood glucose control using a targeted pharmacotherapy protocol compared to current protocol
Timepoint
Blood glucose measurement at baseline, during hospitalization (during ICU stay in the pre-protocol phase every 6 hours and in the protocol phase every 1 to 4 hours; during hospitalization in the ward, fasting, before lunch, before dinner, and at bedtime) and after discharge on days 15, 30, 60, and 90.
Method of measurement
Blood test (venous blood glucose level) or glucometer (capillary blood glucose level)

Secondary outcomes

1

Description
Comparison of targeted pharmacotherapy protocol with current protocol on the incidence of any infection in liver transplant recipients within 3 months after transplantation
Timepoint
During hospitalization and after discharge on days 15, 30, 60, and 90
Method of measurement
Based on the criteria for each infection, positive culture, antibiotic regimen for more than 3 days, and confirmation by the infectious disease service

2

Description
Comparison of targeted pharmacotherapy protocol with current protocol on mechanical ventilation in liver transplant recipients during hospitalization

Timepoint
During hospitalization
Method of measurement
Patient's medical records

3

Description
Comparison of targeted pharmacotherapy protocol with current protocol on length of hospitalization in liver transplant recipients
Timepoint
During hospitalization
Method of measurement
Patient's medical records

4

Description
Comparison of targeted pharmacotherapy protocol with current protocol on the incidence of acute kidney injury or need for dialysis in liver transplant recipients within 3 months after transplantation
Timepoint
During hospitalization and after discharge on days 15, 30, 60, and 90
Method of measurement
KDIGO criteria

5

Description
Comparison of targeted pharmacotherapy protocol with current protocol on the incidence of graft rejection in liver transplant recipients within 3 months after transplantation
Timepoint
During hospitalization and after discharge on days 15, 30, 60, and 90
Method of measurement
An unexplained two times or more of AST/ALT and normalization following 3 days of pulse methylprednisolone, definitive diagnosis and severity of graft rejection by liver biopsy and using Banff criteria

6

Description
Comparison of targeted pharmacotherapy protocol with current protocol on the incidence of new-onset diabetes after transplantation in liver transplant recipients
Timepoint
During hospitalization and after discharge on days 15, 30, 60, and 90
Method of measurement
blood glucose level

7

Description
Comparison of targeted pharmacotherapy protocol with current protocol on mortality rate of liver transplant recipients within 3 months after transplantation
Timepoint
During hospitalization and after discharge on days 15, 30, 60, and 90
Method of measurement
Patient's medical records

Intervention groups

1

Description
Control group: Blood glucose control according to current protocol
Category
Treatment - Other

2

Description
Intervention group: Blood glucose control based on a targeted pharmacotherapy protocol
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital complex
Full name of responsible person
Yekta Rameshi
Street address
Imam Khomeini hospital complex
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ramin Kordi
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141765383761

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vcr@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Yekta Rameshi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to

make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available