

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Aug 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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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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