

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Evaluation of short term outcomes of liver transplantation from COVID-19 positive deceased donors

Protocol summary

Study aim

Evaluation of early outcomes of liver transplantation from COVID-19 positive deceased donors and risk of transmission of COVID-19 in liver transplant

Design

Non-randomized non-inferiority single arm clinical trial on 10 patients requiring urgent liver transplantation

Settings and conduct

Conditions for organ harvesting: Harvest operation will be performed in the operating room of Imam Reza hospital (COVID-19 center), in accordance with all health protocols, and the harvested liver will be transferred to the transplant hospital for transplantation. Patient follow up: postoperatively patients will be visited daily by surgeons, hepatologists and infectious disease specialists. In case of suspicion for COVID-19, PCR and lung HRCT will be performed. For all patients, two PCR tests will be done respectively in day 7 and 14 postoperatively.

Participants/Inclusion and exclusion criteria

Recipients: patients with acute liver failure requiring urgent liver transplantation without any clinical manifestation of COVID-19 and No lung involvement in HRCT and negative PCR test. Donors: Deceased due to non respiratory failure / positive COVID-19 PCR test or lung involvement in HRCT

Intervention groups

Harvesting liver from COVID-19 positive deceased donors and transplant to patients requiring urgent liver transplantation

Main outcome variables

Early outcomes of liver transplantation; transmission of COVID-19

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200928048867N1**

Registration date: **2020-10-22, 1399/08/01**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-22, 1399/08/01**

Update count: **0**

Registration date

2020-10-22, 1399/08/01

Registrant information

Name

Sara Saeidi Shahri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3845 8671

Email address

saeidis971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-01, 1399/07/10

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of short term outcomes of liver transplantation from COVID-19 positive deceased donors

Public title

Evaluation of short term outcomes of liver

transplantation from COVID-19 positive deceased donors

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Recipients with acute liver failure and MELD score > 20 requiring urgent liver transplant. Recipients should have Negative PCR test/ NO COVID-19 signs and symptoms/ NO lung involvement in HRCT. Deceased donors with positive PCR tests or COVID-19 lung involvement in HRCT.

Exclusion criteria:

Recipients with clinical presentation of COVID-19 OR positive PCR test OR lung involvement in HRCT. Deceased donors due to respiratory failure.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 10

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

Ethics committee of Mashhad University of Medical Sciences

Street address

General Surgery Department, Imam Reza Hospital, Ibnesina St.

City

Mashhad

Province

Razavi Khorasan

Postal code

009851

Approval date

2020-09-26, 1399/07/05

Ethics committee reference number

IR.MUMS.REC.1399.442

Health conditions studied

1

Description of health condition studied

Acute liver failure

ICD-10 code

K74

ICD-10 code description

Fibrosis and cirrhosis of liver

Primary outcomes

1

Description

Description of early outcomes of liver transplant from COVID-19 positive deceased donors

Timepoint

30 days within operation

Method of measurement

Clinical assessments/ liver functional tests

2

Description

Evaluation of transmission of COVID-19

Timepoint

24 hours, day 7 and 14 postoperatively

Method of measurement

Clinical manifestations, PCR test, lung HRCT

Secondary outcomes

1

Description

Long term outcomes of liver transplant from COVID-19 positive deceased donors

Timepoint

6 months and 1 year postoperatively

Method of measurement

Clinical follow ups and liver function tests

Intervention groups

1

Description

Intervention group: Patients with acute liver failure requiring urgent liver transplant

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Transplant center of Montaserieh

Full name of responsible person

Mohsen Aliakbarian

Street address

Montaserieh Hospital, Golsestan St., Imam Khomeini Ave.

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Sara Saeidi Shahri

Position

Resident of General Surgery

Latest degree

Medical doctor

Other areas of specialty/work

Transplantation

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

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Ghoreshi building, Daneshgah Ave.

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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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Aliakbarian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Sara Saeidi Shahri

Position

Resident of Geneal Surgery

Latest degree

Medical doctor

Other areas of specialty/work

Transplantation

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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

IPD collected for the primary outcome measures are to be shared.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

It's only available for people working in academic institutions

Under which criteria data/document could be used

Requests for sharing data should be sent to the person responsible for general inquiries.

From where data/document is obtainable

Requests for sharing data should be sent to the person responsible for general inquiries. Sara Saeidi Shahri saeidis971@mums.ac.ir 00989156846143

What processes are involved for a request to access data/document

Requests should be accepted by scientific and executive team of study, then the data will be shared.

Comments