Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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 failue and MELD score> 20 requiring urgent liver transplant Recipients should have Negetive 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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