

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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.

**City**

Mashhad

**Province**

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**Postal code**

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**Phone**

+98 51 3229 1963

**Email**

Aliakbarianm@mums.ac.ir

Sara Saeidi Shahri

**Position**

Resident of General Surgery

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Transplantation

**Street address**

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**Fax****Email**

saeidis971@mums.ac.ir

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Ghoreshi building, Daneshgah Ave.

**City**

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**Province**

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**Postal code**

9138813944

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tafaghodim@mums.ac.ir

**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**

Transplantation

**Street address**

General Surgery Department, Imam Reza Hospital, Ibnesina St.

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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**