

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Clinical evaluation of organ preservation HTK solution in clinical liver transplantation: a pilot randomized phase three clinical trial study

Protocol summary

Study aim

Evaluating the efficacy and safety of a locally produced organ preservation and perfusion solution similar to the imported product called Custodial HTK solution in clinical liver transplantation

Design

This is a pilot, randomized, single-blind, phase III parallel design clinical trial study comparing two organ perfusion solutions among 28 candidates for liver transplantation. The randomization sequence for the two comparison groups was generated with an online program available at <https://www.sealedenvelope.com/simple-randomiser/v1/lists>.

Settings and conduct

The study was conducted in the Shiraz Transplant Center located in Abu Ali Sina Hospital, Shiraz, Iran. Candidates for liver transplantation were categorized in two groups. The intervention group received a locally produced organ preservation and perfusion solution similar to the imported product Custodial HTK solution. The control group received the Custodial HTK solution. Patients were blinded to the perfusion solution patients have received.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patient undergoing liver transplantation; age above 18 years old; informed consent to enter the study. Exclusion criteria: those with organ donations from outside of the province; pregnant patients or those who are lactating; those with donations after cardiac death (DCD); those who are undergoing re-transplantations and those with machine perfusion.

Intervention groups

The intervention group received a locally produced organ preservation and perfusion solution similar to the imported product Custodial HTK solution. The control group received the Custodial HTK solution.

Main outcome variables

Primary non-function of liver; changes in AST and ALT on the first day after transplantation up to the day of

discharge; acute rejection during first month; early patient survival (3 months); biliary complications

General information

Reason for update

The block size was a typo (an error in data entry within the website).

Acronym

IRCT registration information

IRCT registration number: **IRCT20200106046029N1**
Registration date: **2021-06-08, 1400/03/18**
Registration timing: **retrospective**

Last update: **2021-10-06, 1400/07/14**

Update count: **1**

Registration date

2021-06-08, 1400/03/18

Registrant information

Name

Manica Negahdaripour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3242 5403

Email address

negahdaripour@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

2019-04-26, 1398/02/06

Actual recruitment end date

2020-08-18, 1399/05/28

Trial completion date

2021-01-25, 1399/11/06

Scientific title

Clinical evaluation of organ preservation HTK solution in clinical liver transplantation: a pilot randomized phase three clinical trial study

Public title

Effect of HTK solution in liver transplantation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient undergoing liver transplantation Age above 18 years old Informed consent to enter the study

Exclusion criteria:

Those with organ donations from outside of the province Pregnant patients or those who are lactating Those with donations after cardiac death (DCD) Those who are undergoing re-transplantations Those with machine perfusion

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **28**

Actual sample size reached: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

The eligible study participants (n=28) were randomized into two study arms (1:1) using the permuted block randomization with a fixed block size of 4. The randomization sequence will be generated with an online program available at <https://www.sealedenvelope.com/simple-randomiser/v1/lits>.

Blinding (investigator's opinion)

Single blinded

Blinding description

The generated random sequence were inserted in opaque envelopes enumerated in sequence from 01 to 28, each of which will be used for consecutive study participants.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

Street address

Administration Building of Shiraz University of Medical Sciences - Zand St.

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2019-08-14, 1398/05/23

Ethics committee reference number

IR.SUMS.REC.1398.626

Health conditions studied**1****Description of health condition studied**

Organ transplantation

ICD-10 code

Z94

ICD-10 code description

Transplanted organ and tissue status

Primary outcomes**1****Description**

Primary non-function of organ

Timepoint

30 days after transplantation

Method of measurement

Blood tests and pathology biopsy

Secondary outcomes**1****Description**

Changes in AST and ALT on the first day after transplantation up to discharge

Timepoint

One day after transplantation up to discharge

Method of measurement

Blood test

2**Description**

Acute rejection during first month

Timepoint

One month after transplantation
Method of measurement
Blood tests and pathology biopsy

3

Description

Early patient survival (3 months)

Timepoint

Three months after transplantation

Method of measurement

Follow-up of patients and hospital records

4

Description

Biliary complications

Timepoint

Three months after transplantation

Method of measurement

follow-up sonography

Intervention groups

1

Description

The intervention group received the HTK perfusion solution (Cmab Fare Zist Inc., Shiraz, Iran) according to routine transplantation protocol.

Category

Treatment - Other

2

Description

The control group received the Custadiol® HTK solution according to routine transplantation protocol.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Abu-Ali-Sina Center for Medicine and Organ Transplant

Full name of responsible person

Saman Nikeghbalian

Street address

Abu-Ali-Sina Center for Medicine and Organ Transplant- Phase 2- Sadra

City

Shiraz

Province

Fars

Postal code

7146864685

Phone

+98 71 3242 5403

Fax

+98 71 1640 3061

Email

monica.negahdaripour@yahoo.com

Web page address

<http://www.shiraztransplant.com/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pharmed Cina Caspian Pouyesh Company

Full name of responsible person

Dr. Manica Negahdari pour

Street address

Center for biotechnology growth, Pardis School of Pharmacy, Karafarin Street, 5 kilometers into the Shiraz-Esfahan Highway

City

Shiraz

Province

Fars

Postal code

7146864685

Phone

+98 71 3242 5257

Fax

+98 71 3242 5257

Email

negahdaripour@sums.ac.ir

Web page address

<http://www.PharMedCina.com/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pharmed Cina Caspian Pouyesh Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Alireza Shamsaeefar

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Hepato Pancreato Biliary Surgery and Abdominal Organ Transplantation Department of Surgery, School of Medicine

Street address

Abu Ali Sina for Medicine & Organ Transplant Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

7146864685

Phone

+98 71 3242 5403

Email

shamsaeefar@yahoo.com

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

Shiraz University of Medical Sciences

Full name of responsible person

Alireza Shamsaeefar

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Hepato Pancreato Biliary Surgery and Abdominal Organ Transplantation Department of Surgery, School of Medicine

Street address

Abu Ali Sina for Medicine & Organ Transplant

City

Shiraz

Province

Fars

Postal code

7146864685

Phone

+98 71 3242 5403

Fax**Email**

shamsaeefar@yahoo.com

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

Shiraz University of Medical Sciences

Full name of responsible person

Manica Negahdaripour

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Shiraz School of Pharmacy- Karafarin St

City

Shiraz

Province

Fars

Postal code

7146864685

Phone

+98 71 3242 5403

Fax

+98 71 3242 5403

Email

monica.negahdaripour@yahoo.com

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