

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Restricted Crystalloid fluid Therapy during Liver Transplant Surgery and Its Effect on Pulmonary and Renal insufficiency in the Early postoperative period. A randomized clinical trial

Protocol summary

Summary

The aim of the present study is evaluation of the relation between intra-operative fluid therapy and early renal and pulmonary complications after liver transplantation. Sixty three patients with end-stage liver disease (ESLD) that undergoing orthotopic deceased donor liver transplantation will be enrolled .They will be randomly divided into two groups including restricted fluid group which will receive a controlled fluid administration of normal saline (5mg/kg/hr during anaesthesia) and non restricted fluid group will receive a continuous controlled infusion of isotonic saline (10ml/kg/hr during anesthesia). Early postoperative pulmonary and renal complications in both groups will be assessed and compared with each other. The patients will be monitored during the three stages of liver transplantation through hemodynamic parameters assessment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013101811662N4**

Registration date: **2013-11-11, 1392/08/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-11-11, 1392/08/20

Registrant information

Name

Mohammad Ali Sahmeddini

Name of organization / entity

Shiraz University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences .

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Restricted Crystalloid fluid Therapy during Liver Transplant Surgery and Its Effect on Pulmonary and Renal insufficiency in the Early postoperative period. A randomized clinical trial

Public title

The effect of restricted fluid therapy on posoperative renal and pulmonary complications following liver transplantation.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Eligible participants are all adult patients with end-stage liver who will candidate for liver transplantation. Exclusion criteria: The patients with history of Asthma; chronic obstructive lung disease;

hepatopulmonary syndrome; hepatopulmonary hypertension; hepatorenal syndrome; renal failure.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **63**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University Medical Research Ethic Committee

Street address

Shiraz University of Medical Sciences ,Zand Blv

City

Shiraz

Postal code

197871345

Approval date

2013-10-06, 1392/07/14

Ethics committee reference number

CT-2013-165

Health conditions studied

1

Description of health condition studied

Liver Transplantation

ICD-10 code

Y83.0

ICD-10 code description

Surgical operation with transplant of whole organ

Primary outcomes

1

Description

Incidence of acute renal failure

Timepoint

1st day postoperation, 2nd day post operation, 3rd day postoperation.

Method of measurement

Acute renal failure is define according to serum creatinine.

2

Description

Incidence of acute respiratory failure

Timepoint

1st day postoperation, 2nd day post operation, 3rd day postoperation.

Method of measurement

By doing arterial blood gas.

Secondary outcomes

1

Description

Heart rate.

Timepoint

30 minutes after surgical incision,at start of anhepatic phase,at start of neohepatic phase.

Method of measurement

By electrocardiogram.

2

Description

Mean arterial blood pressure.

Timepoint

30 minutes after surgical incision,at start of anhepatic phase,at start of neohepatic phase.

Method of measurement

By arterial catheter in radial artery(mmHg)

3

Description

Cardiac output.

Timepoint

30 minutes after surgical incision,at start of anhepatic phase,at start of neohepatic phase.

Method of measurement

By NICO system for measuring noninvasive CO.

4

Description

Central venous pressure.

Timepoint

30 minutes after surgical incision,at start of anhepatic phase,at start of neohepatic phase.

Method of measurement

By internal jugular catheter.

Intervention groups

1

Description

In the restricted fluid group. patients received 5 ml/kg/hr crystalloid fluid during anesthesia for orthotopic liver transplantation.

Category

Treatment - Other

2

Description

In the non restricted fluid group, patients received 10ml/kg/hr crystalloid fluid during anesrthesia for orthotopic liver transplantation

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital Organ Transplantation Center

Full name of responsible person

Mohammad Ali Sahmeddini

Street address

Namazi Hospital, Namazi Sq

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellery of Research and Technology

Full name of responsible person

Dr.Gholamreza Hatam

Street address

Shiraz University Of Medical Sciences building,Zand Blv

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Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-Chancellery of Research and Technology

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University Of Medical Sciences

Full name of responsible person

Mohammad Ali Sahmeddini

Position

Associate Professor of Anesthesiology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty