Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Intraoperative Restricted Normal Saline during Orthotopic Liver Transplantation on Amount of Administered Sodium Bicarbonate

Protocol summary

Summary
The aim of this study is determining whether the restricted use of normal saline during anesthesia reduce the need for NaHCO3. In this study, seventy five patients with end-stage liver disease who will undergo OLT from Feb 2013 to December 2013 in the Shiraz organ transplantation center will be enrolled and fluid managements of two different transplant anesthetics will be compared. The effect of restricted normal saline fluid will be compared with non restricted normal saline fluid on hemodynamic and acid-base parameters at three times during OLT: 30 minutes after the skin incision (T1), 15 minutes before reperfusion (T2), and 5 minutes after reperfusion (T3).

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2013110711662N5**
Registration date: **2013-11-24, 1392/09/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2013-11-24, 1392/09/03

Registrant information
Name
Mohammad Ali Sahmeddini
Name of organization / entity
Shiraz University Of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source
Shiraz University of Medical Sciences

Expected recruitment start date
2013-02-01, 1391/11/13
Expected recruitment end date
2013-12-31, 1392/10/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Intraoperative Restricted Normal Saline during Orthotopic Liver Transplantation on Amount of Administered Sodium Bicarbonate

Public title
The effect of restricted normal saline on the volume of sodium bicarbonate use during liver transplantation.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: All adult patients with end-stage liver disease aged 16 and more,who will be underwent orthotropic deceased donor liver transplantation.
Exclusion criteria:patients with hepatorenal syndrome type I& II; baseline serum potassium more than 6 meq/l; hepatopulmonary syndrome; portopulmonary hypertension; cardiac ejection fraction less than 60%; cirrhotic cardiomyopathy.
Age
From **16 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **75**
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
2013-11-09, 1392/08/18
Ethics committee reference number
CT-2013-170

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
was sodium bicarbonate dosage that will used during surgery
Timepoint
At the end of hepatectomy phase
Method of measurement
According to usage volume (ml)

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
Central venous pressure
Timepoint
30 minutes after surgical incision,at start of anhepatic phase,at start of neohepatic phase
Method of measurement
By internal jagular 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
N/A

2

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

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

City

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