

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

sahmeddini@sums.ac.ir

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).

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

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

Country

Iran (Islamic Republic of)

Phone

+98 71 1231 8072

Email address

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 orthotopic 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 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

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**Street address**

Shiraz Anesthesiology and Critical Care Research
Center, Namazi Hospital, Namazi Sq.

City

Shiraz

Postal code

7193711351

Phone

+98 71 1647 4270

Fax

+98 71 1647 4270

Email

sahmeddini@sums.ac.ir

Web page address

<http://sacrc.sums.ac.ir>

Person responsible for scientific 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**Street address**

Shiraz Anesthesiology and Critical Care Center,
Namazi Hospital, Namazi Sq

City

Shiraz

Postal code

7193711351

Phone

+98 71 1647 4270

Fax

+98 71 1647 4270

Email

sahmeddini@sums.ac.ir

Web page address

<http://sacrc.sums.ac.ir>

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University Of Medical Sciences

Full name of responsible person

MohammadAli Sahmeddini

Position

Associate Professor of Anesthesiology

Other areas of specialty/work**Street address**

Shiraz Anesthesiology and Critical Care Research
Center, Namazi Hospital, Namazi Sq

City

Shiraz

Postal code

7193711351

Phone

+98 71 1647 4270

Fax

+98 71 1647 4270

Email

sahmeddin@sums.ac.ir

Web page address

<http://sacrc.sums.ac.ir>

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