

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of aminophyllin on renal function after liver transplant surgery

Protocol summary

Study aim

The effect of Aminophylline on renal function after liver transplant surgery

Design

Double blinded randomized clinical trial

Settings and conduct

Methods: 100 patients who are undergoing liver transplantation will included to the study in Namazi Hospital, Shiraz, two groups A and B are considered. Patients in the intervention group receive 5 mg / kg of aminophylline as bolus after induction of anesthesia and then receive aminophylline infusion at a dose of 0.25 mg / kg / hour to 48 hours post-operatively. In the control group patients at the same times receive normal saline. Blinding:According to the selected dose of aminophylline, 0.25 micrograms per kilogram per hour, a 50-cc syringe of aminophylline (1cc /25 mg) is provided for the intervention group in the operating room and placed in a pump syringe for prescribing the drug in ICU.

Participants/Inclusion and exclusion criteria

Inclusion Criteria:All patients who are undergoing liver transplant surgery. Exclusion Criteria:History of cardiac arrhythmia Tachycardia Renal injury Obstructive uropathy Congenital anomalies of the kidney Creatinine above 1.5 Sodium level less than 135 Patients who use of donated cadaver liver.

Intervention groups

Patients in the intervention group receive 5 mg / kg of aminophylline as bolus after induction of anesthesia and then receive aminophylline infusion at a dose of 0.25 mg / kg / hour to 48 hours post-operatively. In the control group patients at the same times receive normal saline.

Main outcome variables

Primary outcome variable: The serum glomerular and creatinine clearance levels are measured before surgery, and after the operation, GFR and serum creatinine are measured every day for up to 5 days in the ICU.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N79**

Registration date: **2019-04-06, 1398/01/17**

Registration timing: **prospective**

Last update: **2019-04-06, 1398/01/17**

Update count: **0**

Registration date

2019-04-06, 1398/01/17

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-05, 1398/02/15

Expected recruitment end date

2019-09-06, 1398/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aminophyllin on renal function after liver

transplant surgery

Public title

The effect of aminophyllin on renal function after liver transplant surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All patients who are undergoing liver transplant surgery.

Exclusion criteria:

History of cardiac arrhythmia Tachycardia Renal injury Obstructive uropathy Congenital anomalies of the kidney Creatinine above 1.5 Sodium level less than 135 Patients who use of donated cadaver liver

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients randomly enter the study through the randomization chart which is derived from the www.randomization.com.

Blinding (investigator's opinion)

Double blinded

Blinding description

According to the selected dose of aminophylline, 0.25 micrograms per kilogram per hour, a 50-cc syringe of aminophylline (1cc /25 mg) is provided for the intervention group in the operating room and placed in a pump syringe for prescribing the drug in ICU.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Shiraz University of Medical Sciences

Street address

Vice chancellor for research, 7th floor of central building of Shiraz University of medical sciences, Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2016-08-22, 1395/06/01

Ethics committee reference number

IR.SUMS.MED.REC.1396.35

Health conditions studied

1

Description of health condition studied

kidney transplant

ICD-10 code

T86.1

ICD-10 code description

Complications of kidney transplant

Primary outcomes

1

Description

Glomerular filtration rate

Timepoint

Before the operation and daily until 5 days post-operatively

Method of measurement

Cochcroft and Gault formula

2

Description

Serum creatinine level

Timepoint

Before the operation and daily until 5 days post-operatively

Method of measurement

Venous blood sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group receive 5 mg / kg of aminophylline as bolus after induction of anesthesia and then receive aminophylline infusion at a dose of 0.25 mg / kg / hour to 48 hours post-operatively.

Category

Prevention

2

Description

Control group: Patients at the same times of intervention group receive normal saline with the same volume of aminophylline, and only use usual care during and after liver transplantation

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Amin Valipour

Street address

Namazi Hospital, Namazi Square

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7134844119

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+98 71 3647 4270

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masihifarzaneh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Yones Ghasemi

Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hossein Eghbal

Position

Fellow ship of Organ Transplantation anesthesiology

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mohammad Hossein Eghbal

Position

Fellow ship of Organ Transplantation anesthesiology

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Farzaneh Masihi
Position
MS in English Teaching, BS in anesthesia/English
Consultant
Latest degree
Master
Other areas of specialty/work
Others
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Shiraz
Province
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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