

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 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](http://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

##### City

Shiraz

##### Province

Fars

##### Postal code

7134844119

##### Phone

+98 71 3647 4270

##### Email

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

##### City

Shiraz

##### Province

Fars

##### Postal code

7134844119

##### Phone

+98 71 3647 4270

##### Email

masihifarzaneh@yahoo.com

##### 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

##### Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

##### City

Shiraz

##### Province

Fars

##### Postal code

7134844119

##### Phone

+98 71 3647 4270

##### Email

hoseineghbal@yahoo.com

## Person responsible for scientific 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

##### Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

##### City

Shiraz

##### Province

Fars

**Postal code**  
7134844119  
**Phone**  
+98 71 3647 4270  
**Email**  
hoseineghbal@yahoo.com

7134844119  
**Phone**  
+98 716474270  
**Email**  
masihifarzaneh@yahoo.com

## 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  
**Street address**  
5th floor, Mohammad Raoul Allah Research Tower,  
Khalili Street  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**

## 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