Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Aminophylline on Renal Function after Cardiac Surgery

Protocol summary

Summary

Objectives: the aim of this study was to assess the effectiveness of aminophylline for prevention of renal impairment after cardiac surgery. Inclusion criteria: all patients undergoing cardiac surgery and can use Aminophylline. Research Design: Conduction of a randomized, double-blind, clinical trial, method of randomization: simple. Exclusion criteria: patients with cardiac arrhythmia, tachycardia, and patients with kidney damage in case of non- oliguric, daily urine of patients who have obstructive uropathy, patients with congenital renal anomalies. One hundred and fourthly-four patients undergoing cardiac surgery were risk stratified as per Cleveland score to assess for prediction of AKI(acute kidney injury). 72 patients in the intervention group received a bolus aminophylline of 5 mg/kg and a subsequent continuous infusion of 0.25 mg/kg/h for up to 48 h, while, 72 Patients of control group just received usual postoperative care. Serum creatinine concentrations were measured preoperatively and daily until 2 days after surgery and the glomerular filtration rate estimated using Cockcroft and Gault formula. Hourly urine output was recorded and patients assigned to respective RIFLE stage of AKI. Cleveland score ≥6 was associated with higher incidence of AKI: I and F. Number needed to treat, an insight into the clinical relevance of a specific treatment, is 8.

General information

Acronym

acute kidney injury (AKI), acute renal failure (ARF)

IRCT registration information

IRCT registration number: **IRCT2015010619470N10**
Registration date: **2015-01-27, 1393/11/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-01-27, 1393/11/07

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2015-01-21, 1393/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Aminophylline on Renal Function after Cardiac Surgery

Public title

The Effect of Aminophylline on Renal after Cardiac Surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: all patients undergoing cardiac surgery and can use Aminophylline. Exclusion criteria: patients with cardiac arrhythmia, tachycardia , patients with kidney damage in case of non oliguric, daily urine of

patients who have obstructive uropathy, patients with congenital renal anomalies

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **144**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic Committee of Shiraz University Of Medical Sciences

Street address
Central Building of Shiraz University of Medical Sciences, Zand Street

City
Shiraz

Postal code

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
CP-P-9374-7224

Health conditions studied

1

Description of health condition studied
Cardiac Surgeries

ICD-10 code
197.1

ICD-10 code description
Cardiac insufficiency Heart failure following cardiac surgery or due to presence of cardiac prosthesis

Primary outcomes

1

Description
Diagnosis of Kidney Damage

Timepoint
Daily measurement: On the days before and after surgery and the second and third days after surgery.

Method of measurement
RIFLE scale: It based on the amount of creatinine and GFR calculated by the amount of kidney damage.

Secondary outcomes

1

Description
Diagnosis of Kidney Damage

Timepoint
Daily measurement: On the days before and after surgery and the second and third days after surgery

Method of measurement
Urine Output

Intervention groups

1

Description
Patients in the intervention group received a bolus aminophylline of 5 mg/kg before the surgery and a subsequent continuous infusion of 0.25 mg/kg/h for up to 48 h after the surgery.

Category
Treatment - Drugs

2

Description
Control group: patients in the control group didn't take aminophylline.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Kowsar Hospital

Full name of responsible person
Peyman Alishahi

Street address
Ghasrodasht Street

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Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Shiraz University of Medical Sciences
Full name of responsible person
Dr Seed Basir Hashemi
Street address
Vice Chancellor for Research, Shiraz University of Medical Sciences, 7th floor, Central Building of Shiraz University of Medical Sciences, Zand Street
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Shiraz University of Medical Sciences
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
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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