Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Survey of the effect of intravenous aminophylline on renal function of brain injury patients with acute renal failure admitted to the intensive care unit

Protocol summary

Study aim

Determination the effect of intravenous aminophylline on renal function of brain injury patients with acute renal failure admitted to the Intensive Care Unit

Design

In this study 50 eligible patients will be selected. Sampling will be performed for 6 months among eligible patients. The patients will be entered into study after hemodynamic symptoms stabilization and the patients will be divided into two groups of control and intervention (each group has 25 people) by using table of random numbers. This study is phase III clinical trial.

Settings and conduct

The study will be done in the two intensive care units of shahid Rahnemoon hospital in Yazd. The samples will be divided into two groups of control and intervention with simple random sampling. In the intervention group, the urine output, BUN (Blood Urea Nitrogen) and creatinine of the patients, 24 hours before the study, will be measured and recorded by the researcher assistant. Then, an aminophylline dose of 0.2 mg / kg / h will be started as an intravenous infusion according to the physician's order and the rate of the renal function will be recorded 24 hours after the start of aminophylline. Control group will receive normal saline 0.9% with the same dose as the intervention group and their scales of renal function will be measured similar to the intervention group. This study is double blinded and researcher and patients are kept blind. Decreasing bias by using table of random numbers and assigning code to patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients 18-65 years old; both sexes; acute renal failure after admission to the intensive care unit; stabilized hemodynamic symptoms Exclusion criteria: contraindications for aminophylline (history of seizure-arrhythmia); patients with a history of renal dysfunction

Intervention groups

In the intervention group, urine output, BUN (Blood Urea Nitrogen) and creatinine of the patients, 24 hours before the study will be measured, and recorded by the assistant researcher. Then, aminophylline 0.2 mg / kg / h will be started for the patient intravenously according to the physician's order and rate of renal function will be recorded 24 hours after starting aminophylline. In the control group, the Patients will receive normal saline 0.9% with the same dose as the intervention group and their scales of renal function will be measured similar to the intervention group.

Main outcome variables

urine output, BUN(Blood Urea Nitrogen), creatinine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171105037246N2**
Registration date: **2018-03-04, 1396/12/13**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-04, 1396/12/13**
Update count: **0**

Registration date

2018-03-04, 1396/12/13

Registrant information

Name

Manijeh Shahriary Kalantary

Name of organization / entity

Islamic Azad University of Yazd

Country

Iran (Islamic Republic of)

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+98 35 3622 2843

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Recruitment status
Recruitment complete
Funding source
Vice Chancellor for Research of SHahhid Sadoughi University of Medical Siences of Yazd

Expected recruitment start date
2017-07-23, 1396/05/01
Expected recruitment end date
2019-03-20, 1397/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Survey of the effect of intravenous aminophylline on renal function of brain injury patients with acute renal failure admitted to the intensive care unit

Public title
Effect of intravenous aminophylline on renal function of brain injury patients with acute renal failure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Brain injury patients after the stabilization of hemodynamic symptoms from both sexes patients with acute renal failure after admission to the intensive care unit 18-65 years old
Exclusion criteria:
Patients with unstable hemodynamic conditions Contraindications for aminophylline History of seizure History of arrhythmia Patients with a history of renal dysfunction
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization of patients will be done by using table of random numbers with the obtained numbers, patients will be assigned to two groups of intervention and control
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double-blinded study and Researcher and patients are kept unaware of intervention in each group.
Placebo
Used
Assignment
Parallel
Other design features
The randomization of study groups will be done by using table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences
Street address
The central building of Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd
City
Yazd
Province
Yazd
Postal code
8916978477
Approval date
2017-04-26, 1396/02/06
Ethics committee reference number
IR.SSU.REC.1396.24

Health conditions studied

1

Description of health condition studied
Brain injury patients with acute renal failure
ICD-10 code
S06.2
ICD-10 code description
Diffuse traumatic brain injury

2

Description of health condition studied
Acute renal failure
ICD-10 code
N17
ICD-10 code description
Acute kidney failure

Primary outcomes

1

Description
Blood Urea Nitrogen

Timepoint
24 hours before and after intervention
Method of measurement
mg/dl

2

Description
Urine output
Timepoint
24 hours before and after intervention
Method of measurement
Ml

3

Description
Creatinin
Timepoint
24 hours before and after intervention
Method of measurement
mg/dl

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, the urine output, BUN and creatinine of the patients, 24 hours before the study, will be measured and recorded by the researcher assistant. Then, an Aminophylline dose of 0.2 mg / kg / h is started as an intravenous infusion acc
Category
Treatment - Drugs

2

Description
The Patients in the control group received normal saline 0.9% in the same dose received in the intervention group and their renal function scales such as the intervention group will be measured.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd Shahid Rahnemoon Hospital
Full name of responsible person
Manijeh Shahriary Kalantary
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Shahid Rahnemoon hospital, Farokhi street, Yazd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor For Research Shahid Sadoughi University of Medical Sciences of Yazd
Full name of responsible person
Dr Amir Hooshahng Mehrparvar
Street address
The Central Building Of Shahid Sadoughi University Of Medical Sciences, Bahonar Square, Yazd
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ah.mehrparvar@gmail.com
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 Shahid Sadoughi University of Medical Sciences of Yazd
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
Islamic Azad University of Yazd
Full name of responsible person
Manijeh Shahriary Kalantary
Position
Master of Critical Care Nursing(Msc), Faculty Member
Latest degree

Master
Other areas of specialty/work
Nursery
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Person responsible for updating data

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Web page address

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
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
Information about the main outcome can be shared.
When the data will become available and for how long
6 months after the results are published
To whom data/document is available
For staff in academic and academic institutions
Under which criteria data/document could be used
Possibility to use the study results and further details of the study method.
From where data/document is obtainable
Manijeh Shahriary Kalanatry
What processes are involved for a request to access data/document
After 1 month the requested files will be sent to the requesting person.
Comments