# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## Comparative study of aminophylline infusion with dopamine infusion in traumatic brain injury patients with renal impairment

### Protocol summary


**Study aim**

The present study aims to compare the efficacy of aminophylline infusion with dopamine infusion in patients with renal dysfunction caused by traumatic brain injury.

**Design**

This study is a blinded clinical trial and will be conducted in parallel and by comparing three types of pharmacotherapy regimes on 60 patients with TBI induced Acute kidney injury in Al-Zahra and Kashani Medical Centers in Isfahan .Patients were randomly divided into three groups using Excel software with random function.

**Settings and conduct**

The present double-blind randomized clinical trial will be conducted at Kashani Training Hospital to compare the clinical effects of dopamine and aminophylline in the treatment of acute kidney injury (AKI) secondary to traumatic brain injury (TBI). The study will be conducted in three groups: aminophylline, dopamine, and placebo. Patients will be randomly assigned to treatment groups. It should be mentioned that patients and examiners will be blinded to the type of intervention.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Patients with traumatic brain injury; aged 18 to 65 years; admitted to the intensive care unit (ICU) due to acute kidney injury (AKI) secondary to trauma; informed consent obtained from patient or legally authorized representative (LAR)

**Intervention groups**

In the first group, aminophylline will be administered by intravenous infusion at a dose of 0.2 mg/kg/h. In the second group, dopamine will be administered by intravenous infusion at a dose of 2 µg/kg/min. In the third group (control group), placebo (normal saline) will be administered by intravenous infusion at a dose of 0%/9.

**Main outcome variables**

Urine output, serum BUN, and creatinine will be measured in patients for 24 hours from the start of the intervention.


### General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20221108056446N8**
Registration date: **2024-05-25, 1403/03/05**
Registration timing: **prospective**

Last update: **2024-05-25, 1403/03/05**
Update count: **0**

**Registration date**

2024-05-25, 1403/03/05

**Registrant information**


**Name**

Mehdi Mahmoodkhani

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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+98 913 686 3733

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mahmoodkhani@med.mui.ac.ir


**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2024-06-11, 1403/03/22

**Expected recruitment end date**

2024-09-21, 1403/06/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparative study of aminophylline infusion with dopamine infusion in traumatic brain injury patients with renal impairment

**Public title**
Comparison of aminophylline infusion with dopamine infusion in patients with kidney dysfunction caused by traumatic brain injuries.
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Confirmed Traumatic brain injury by neurological surgeon TBI induced acute kidney injury
**Exclusion criteria:**
Hemodynamic instability Contraindication for of aminophylline or dopamine administration
**Age**
From **18 years** old to **65 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Participant
- Investigator

**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Patient are placed in three groups by random block method. With the easy sampling method, the referring people who are eligible to enter the study are randomly divided into three groups. In this study, the classification of people is done by the four permutation block method. In this method, A represents a person who undergoes surgery with a routine method, and B represents a person who undergoes surgery with a new method. Considering the block of three, we give code 0 to ABC permutation, code 1 to BAC permutation, code 2 to CBA, code 3 to CAB, code 4 to ACB and code 5 to BCA. Then, using the table of random numbers, we randomly select a starting point and then consider the numbers in rows or columns. Considering the order of the numbers in the table, we place the corresponding permutation on each number we come across.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Patients and physicians were unaware of the intervention group and the drugs were pre-prepared and will be injected into patients based on labels A, B, C. It should be noted that patient data will also be recorded based on their intervention label.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences
**Street address**
Hazar Jarib Street, Azadi Square
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174673461
**Approval date**
2023-09-25, 1402/07/03
**Ethics committee reference number**
IR.MUI.MED.REC.1402.222

## Health conditions studied

### 1

**Description of health condition studied**
Acute kidney injury
**ICD-10 code**
N17.0
**ICD-10 code description**
Acute kidney injury

### 2

**Description of health condition studied**
Traumatic brain injury
**ICD-10 code**
S06.2X
**ICD-10 code description**
Diffuse traumatic brain injury

## Primary outcomes

### 1

**Description**
Urinary output
**Timepoint**
24 hours after injection
**Method of measurement**
Urine collection

### 2

**Description**
BUN level
**Timepoint**
24 hours after injection

**Method of measurement**
Blood test

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group 1: Receive aminophylline at a dose of 0.2 mg/kg/h
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group 2: Receive dopamine at a dose of 2 µg/kg/min
**Category**
Treatment - Drugs

### 3

**Description**
Control group: Receive normal saline
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Kashani Hospital
**Full name of responsible person**
Seyed Taghi Hashemi
**Street address**
Kashani Street
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81839 83434
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Gholamreza Asgari
**Street address**
Hazar Jarib Street, Azadi Square
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**Email**
mui@mui.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Esfahan 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**
Esfahan University of Medical Sciences
**Full name of responsible person**
Seyed Taghi Hashemi
**Position**
Associate professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Anesthesiology
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## Person responsible for updating data

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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