

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

KDIGO guidelines effects in Cardiac surgery patients, prone to Acute Kidney Injury

Protocol summary

Study aim

To find the KDIGO guidelines effects in Cardiac surgery patients, prone to Acute Kidney Injury.

Design

Randomised, superiority, parallel group trial with blinded outcome assessment. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site

Settings and conduct

Study was conducted at Afridi medical complex, Peshawar. The outcome assessor was blinded in the study.

Participants/Inclusion and exclusion criteria

Inclusion: Age 50-80 years with both gender. Participants who maintain central venous pressure (CVP) between 8 and 10 mmHg and mean arterial pressure (MAP) >65 mmHg. Exclusion: Patients with end-stage renal disease on dialysis, recent kidney transplantation and contraindications for participation (e.g., pregnancy, severe comorbidities).

Intervention groups

Experimental group: Patients in the intervention group underwent a rigorously controlled administration of the KDIGO recommendations (the "KDIGO CT surgery bundle"), which included the consequent actions: avoiding nephrotoxic substances, stopping angiotensin II receptor blockers (ARBs) and angiotensin converting enzyme inhibitors (ACEi) for the first forty eight hours following operation. Control Group: The standard of treatment for persons in the control group included instructions to maintain central venous pressure (CVP) between 8 and 10 mmHg and mean arterial pressure (MAP) >65 mmHg. As soon as the hemodynamic status stabilized and hypertension appeared, patients were given angiotensin converting enzyme inhibitors (ACEi) or angiotensin II receptor blockers (ARBs).

Main outcome variables

The incidence of AKI within the first 72 hours following heart surgery served as the main variable.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230907059376N6**

Registration date: **2024-10-02, 1403/07/11**

Registration timing: **retrospective**

Last update: **2024-10-02, 1403/07/11**

Update count: **0**

Registration date

2024-10-02, 1403/07/11

Registrant information

Name

Sarmad Khattak

Name of organization / entity

Rehman Medical Institute, Peshawar

Country

Pakistan

Phone

+92 91 5838666

Email address

sarmadkhattak007@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-27, 1400/12/08

Expected recruitment end date

2023-02-21, 1401/12/02

Actual recruitment start date

2022-02-24, 1400/12/05

Actual recruitment end date

2023-03-23, 1402/01/03

Trial completion date

2023-03-27, 1402/01/07

Scientific title

KDIGO guidelines effects in Cardiac surgery patients, prone to Acute Kidney Injury

Public title

KDIGO guidelines effects in Cardiac surgery patients, prone to Acute Kidney Injury. A Randomized Control Trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Maintain central venous pressure (CVP) between 8 and 10 mmHg Mean arterial pressure (MAP) >65 mmHg

Exclusion criteria:

Hyperglycemia Urinary [TIMP-2].[IGFBP7] ≥ 0.3

Age

From **50 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **86**

Actual sample size reached: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization process for the study will utilize simple randomization through a computer-generated random number sequence, ensuring that each participant has an equal chance of being assigned to either the intervention group (KDIGO guidelines) or the control group (standard care). The unit of randomization will be the individual participant, allowing for direct comparisons of outcomes between the two groups. While stratified randomization is not planned, if it were implemented, it would involve defining strata based on key variables such as age or baseline renal function to ensure balanced representation. The randomization will be facilitated by secure computer software that generates the random sequence, which will be prepared before participant recruitment begins to eliminate any potential biases. To maintain allocation concealment, sealed opaque envelopes containing the group assignments will be used; these will only be opened after a participant has been enrolled and consented. This rigorous approach to randomization aims to enhance the integrity of the study, ultimately providing reliable results on the effects of KDIGO guidelines on Acute Kidney Injury in cardiac surgery patients.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, assessors will be blinded to participants' group allocations to minimize bias in outcome evaluation. A separate third-party team will collect and analyze data, ensuring that assessors remain unaware of whether participants are in the intervention or control group. All outcome measurements will be coded,

preventing any influence on their evaluations. This double-blind approach aims to enhance the validity of the findings regarding the impact of KDIGO guidelines on Acute Kidney Injury in cardiac surgery patients.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Afridi Medical Complex ethical committee

Street address

Afridi medical complex tehal payan, University Rd, Tehkal, Peshawar, Khyber Pakhtunkhwa

City

Peshawar

Postal code

25150

Approval date

2022-02-01, 1400/11/12

Ethics committee reference number

AMC/REC/2022/12

Health conditions studied**1****Description of health condition studied**

Acute kidney disease

ICD-10 code

N17

ICD-10 code description

Acute kidney failure

Primary outcomes**1****Description**

The incidence of Acute kidney injury within the first 72 hours following heart surgery served as the main objective.

Timepoint

The degree of acute kidney injury within seventy two hours, the thirty, sixty, and ninety days.

Method of measurement

KDIGO standards

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group underwent a rigorously controlled administration of the KDIGO recommendations (the "KDIGO CT surgery bundle"), which included the consequent actions: avoiding nephrotoxic substances, stopping angiotensin II receptor blockers (ARBs) and angiotensin converting enzyme inhibitors (ACEi) for the first forty eight hours following operation, closely recording urine output and serum creatinine, avoiding hyperglycemia for the first seventy two hours postoperatively, considering substitutes to radiocontrast substances, and closely observing hemodynamics.

Category

Treatment - Drugs

2

Description

Control group: The standard of treatment for persons in the control group included instructions to maintain central venous pressure (CVP) between 8 and 10 mmHg and mean arterial pressure (MAP) >65 mmHg. As soon as the hemodynamic status stabilized and hypertension appeared, patients were given angiotensin converting enzyme inhibitors (ACEi) or angiotensin II receptor blockers (ARBs).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afridi Medical Complex, Peshawar

Full name of responsible person

Mehboob Khan

Street address

Afridi medical complex tehkal payan, University Rd,
Tehkal, Peshawar, Khyber Pakhtunkhwa

City

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Postal code

25150

Phone

+92 91 5711751

Email

mehbob509@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Afridi Medical Complex, Peshawar

Full name of responsible person

Mahboob Khan

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Afridi medical complex tehkal payan, University Rd,
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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

Afridi Medical Complex, Peshawar

Proportion provided by this source

50

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Afridi Medical Complex, Peshawar

Full name of responsible person

Mahboob Khan

Position

Consultant Neurosurgeon

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

KDIGO guidelines effects in Cardiac surgery patients,
prone to Acute Kidney Injury. A Randomized Control Trial

When the data will become available and for how long

Data will be available after 6 months of publication for 1
year.

To whom data/document is available

The data will be available to all the doctors.

Under which criteria data/document could be used

Data will be used just for education.

From where data/document is obtainable

Data will be obtained from corresponding author
mentioned in journal after publication.

What processes are involved for a request to access data/document

Person should email the corresponding author and wait
for response in one week.

Comments