Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 fourty 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

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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 tehkal 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 inury within seventy two hours, the thirty, sixty, and ninty 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 fourty 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Afridi Medical Complex, Peshawar

Full name of responsible person
Mahboob Khan

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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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Person responsible for scientific

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