

Renoprotection with hydration

Submission date 10/10/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/11/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/11/2023	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The aim of this study is to determine the effect of giving intravenous saline (0.9%) hydration before open heart surgery on kidney function after surgery and the prevention of acute kidney injury.

Who can participate?

Patients aged 18 to 85 years with normal kidney function who are undergoing cardiac surgery

What does the study involve?

Participants are randomly allocated to one of two groups. The first group (control group) will have fluid restriction for 12 hours before surgery and the second group (case group) will be hydrated with 0.9% normal saline for 12 hours before surgery.

What are the possible benefits and risks of participating?

This study aims to prevent kidney injury with a basic low-cost technique. The researchers monitor the participants to prevent hypervolemia (fluid overload) so are no risks expected.

Where is the study run from?

Kartal Koşuyolu High Specialization Training and Research Hospital (Turkey)

When is the study starting and how long is it expected to run for?

June 2020 to December 2021

Who is funding the study?

Kartal Koşuyolu High Specialization Training and Research Hospital (Turkey)

Who is the main contact?

Mrs Ayse Zehra Karakoc, aysezehra.karakoc@saglik.gov.tr (Turkey)

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

Protocol serial number

Nil known

Study information**Scientific Title**

The effect of preoperative hydration on cardiac surgery-associated acute kidney injury

Study objectives

The hypothesis of this study is that preoperative intravenous saline (0.9%) hydration can prevent postoperative cardiac surgery-associated acute kidney injury instead of the traditional dehydration protocols prior to surgery

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 22/09/2020, Health Sciences University Kartal Kosuyolu High Specialization Training and Research Hospital's Clinical Research Ethics Committee (Denizer st. Cevizli Avenue, Istanbul, 34865, Türkiye; +90 (0)2165001500; aysezhrakarakoc@gmail.com), ref: 2020/8/36122/09/2020

Study design

Prospective randomized controlled study

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Open-heart surgery in patients with a glomerular filtration rate (GFR) >45 ml/min/1.73 m², not undergoing dialysis, and without ventricular dysfunction

Interventions

G-power analysis was used to determine the total sample size and with an effect size of 0.48 (alpha error probability=0.05) and a power value of 0.80, the total required sample size was found to be 110 (at least 55 patients for each group). SPSS v.23 software package was used for data analysis. Patients scheduled for open-heart surgery between October 2020 and December 2020 at Kosuyolu Heart Hospital, with a GFR >45 ml/min/1.73 m², not undergoing dialysis, and without ventricular dysfunction, were randomly divided into two groups. The first group was left with fluid restriction overnight before surgery, while the second group was subjected to preoperative 12-hour intravenous hydration with 0.9% saline. During this process, their total fluid intake and outputs were monitored to avoid any hypervolemia.

Intervention Type

Other

Primary outcome(s)

BUN, creatinine, and GFR values and blood gas values (pH, lactate, HCO₃, Na⁺⁺, K⁺, etc.) measured on postoperative days 0, 1, 2, 3, and 7, and at the first month and the first year

Key secondary outcome(s)

1. Total drainage recorded during the hospital stays of the patients
2. ICU stay recorded during the hospital stays of the patients
3. Total hospital stay recorded during the hospital stays of the patients
4. Extubation times recorded during the hospital stays of the patients

Completion date

31/12/2021

Eligibility

Key inclusion criteria

1. Undergoing an open heart surgery procedure with cardiopulmonary bypass
2. GFR >45 ml/min/1.73 m²
3. Not undergoing dialysis
4. Normal left and right ventricular functions

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

85 years

Sex

All

Total final enrolment

110

Key exclusion criteria

Patients undergoing emergency surgery, aortic dissection and complex aortic surgery patients, congenital heart surgery patients, minimal invasive and redo patients

Date of first enrolment

01/10/2020

Date of final enrolment

31/12/2020

Locations

Countries of recruitment

Türkiye

Study participating centre

Health Sciences University Kartal Kosuyolu High Specialization Training and Research Hospital
Denizer st Cevizli avenue Kartal
Istanbul
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Sponsor information

Organisation

Kartal Koşuyolu High Specialization Training and Research Hospital

ROR

<https://ror.org/054q9np86>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Kartal Koşuyolu High Specialization Training and Research Hospital

Results and Publications

Individual participant data (IPD) sharing plan

While the entire dataset is not publicly accessible to protect individuals' privacy, a subset of the data (excluding patients' names and IDs) will be shared on reasonable request to Ayse Zehra Karakoc (aysezehra.karakoc@saglik.gov.tr)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			03/11/2023	No	No