ISRCTN10684639 https://doi.org/10.1186/ISRCTN10684639

Renoprotection with hydration

Submission date	Recruitment status	[_] Prospectively registered
10/10/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/11/2023	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/11/2023	Digestive System	

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

ClinicalTrials.gov (NCT)
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; aysezehrakarakoc@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 m^2, 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
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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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes