

# Renoprotection with hydration

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<b>Registration date</b> 06/11/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/11/2023	<b>Condition category</b> 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](mailto:aysezehra.karakoc@saglik.gov.tr) (Turkey)

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Prevention

### **Participant information sheet**

Not available in web format, please use the contact details to request a participant information sheet

### **Health condition(s) or problem(s) studied**

Open-heart surgery in patients with a glomerular filtration rate (GFR)  $>45$  ml/min/1.73 m<sup>2</sup>, 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 m<sup>2</sup>, 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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/06/2020

**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 m<sup>2</sup>
3. Not undergoing dialysis
4. Normal left and right ventricular functions

**Participant type(s)**

Patient

**Age group**

Mixed

**Lower age limit**

18 Years

**Upper age limit**

85 Years

**Sex**

Both

**Target number of participants**

110

**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

Türkiye

34865

## **Sponsor information**

**Organisation**

Kartal Koşuyolu High Specialization Training and Research Hospital

**Sponsor details**

Denizer st Cevizli Avenue Kartal

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**Sponsor type**

Hospital/treatment centre

**Website**

kosuyolu@saglik.gov.tr

**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

### Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

### Intention to publish date

11/11/2023

### 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?
<a href="#">Basic results</a>			03/11/2023	No	No