

# Vitamin C and its effect on the kidneys after open heart surgery

|                                        |                                                              |                                                                                                   |
|----------------------------------------|--------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>02/07/2018   | <b>Recruitment status</b><br>No longer recruiting            | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>30/11/2018 | <b>Overall study status</b><br>Completed                     | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>08/06/2022       | <b>Condition category</b><br>Urological and Genital Diseases | <input type="checkbox"/> Individual participant data                                              |

## Plain English summary of protocol

### Background and study aims

Loss of kidney function after heart surgery is a complex complication with high mortality (death rate). The aim of this study is to find out whether Vitamin C supplementation decreases the loss of kidney function after open heart surgery.

### Who can participate?

Adult patients requiring open heart surgery

### What does the study involve?

Participants are randomly allocated to either receive vitamin C or not (control group) before surgery, during surgery and for 5 days after surgery. Kidney function is assessed during surgery and for 5 days after surgery.

### What are the possible benefits and risks of participating?

Vitamin C could be potentially a potent kidney protective agent, with practically no expected side effects or risks.

### Where is the study run from?

1. University Medical Center Maribor (Slovenia)
2. Institute of Cardiovascular Diseases Vojvodina (Serbia)

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

November 2017 to September 2020

### Who is funding the study?

University Medical Center Maribor (Slovenia)

### Who is the main contact?

Assoc. Prof. Miha Antonic, MD, PhD

## Contact information

**Type(s)**

Public

**Contact name**

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**Additional identifiers****Protocol serial number**

2017-2020

**Study information****Scientific Title**

Effect of ascorbic acid supplementation on acute kidney injury after open heart surgery

**Study objectives**

1. Ascorbic acid supplementation decreases loss of kidney function in all surgeries
2. Ascorbic acid supplementation decreases loss of kidney function in urgent surgeries
3. Ascorbic acid supplementation decreases loss of kidney function in patients with decreased kidney function and are not on renal replacement therapy (RRT)
4. The main mechanism for acute kidney injuries (AKI) after cardiovascular surgeries is via reactive oxygen species (ROS) and their effect on lipid peroxidation

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Slovenian National Ethics Committee, 22/05/2018, ref: 0120-268/2018/4

**Study design**

Interventional randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Prevention

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

Acute kidney injury

## **Interventions**

Patients will be randomized according to their day of birth - the ones on even days will be the control group (no supplement) and the ones on odd days will be the test group (supplement).

Ascorbic acid supplementation protocol:

Before surgery (best in the OR, during intubation/central venous catheter placement/arterial line placement): 2 g

During surgery (best immediately before decross-clamping of aorta): 2 g

Postoperative day (POD) 1: 1 g/8 h

POD 2: 1 g/8 h

POD 3: 1 g/8 h

POD 4: 1 g/8 h

POD 5: 1 g/8 h

In total: 19 g

The trialists will observe two levels in this study: clinical and molecular. In Maribor alone, gas chromatography and mass spectrometry will be used to determine malondyaldehyde concentration in the serum of a subgroup of operated patients. Malondyaldehyde has been shown as a relevant measuring tool for ROS involvement in lipid peroxidation. It is assumed that it is following a linear model: the more the malondyaldehyde in serum, the more ROS in the body. Approximately 100 patient (a subgroup of all included patients) will be divided into two subgroups (depending on ascorbic acid supplementation), their serum samples will be collected intraoperatively, and once a day five days postoperatively to determine malondyaldehyde concentration as a function of time.

On the other hand, the trialists will examine the clinical level in all enrolled 400 patients at both institutions (Maribor and Sremska Kamenica). Through creatinine and urea levels, glomerular filtration rate and diuresis, kidney function will be assessed, starting intraoperatively and once a day five days postoperatively.

## **Intervention Type**

Supplement

## **Primary outcome(s)**

Kidney function assessed using creatinine and urea levels, glomerular filtration rate and diuresis, starting intraoperatively and once a day five days postoperatively

## **Key secondary outcome(s))**

ROS involvement in lipid peroxidation, assessed using malondyaldehyde concentration in serum measured using gas chromatography and mass spectrometry, starting intraoperatively and once a day five days postoperatively

## **Completion date**

30/09/2020

## **Eligibility**

### **Key inclusion criteria**

All adult patients requiring open heart surgical procedures, regardless of the urgency (urgent vs elective) or type of procedure (coronary revascularization, valvular surgery or aortic surgery)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

332

**Key exclusion criteria**

1. Chronic kidney failure on renal replacement therapy
2. Hyperoxalouria
3. History of kidney stones

**Date of first enrolment**

01/12/2018

**Date of final enrolment**

31/05/2019

**Locations****Countries of recruitment**

Serbia

Slovenia

**Study participating centre**

**University Medical Center Maribor**

Ljubljanska ulica 5

Maribor

Slovenia

2000

**Study participating centre**

**Institute of Cardiovascular Diseases Vojvodina**

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Sremska Kamenica

Serbia

21204

# Sponsor information

## Organisation

University Medical Center Maribor

## ROR

<https://ror.org/02rjj7s91>

# Funder(s)

## Funder type

University/education

## Funder Name

University Medical Center Maribor

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Assoc. Prof. Miha Antonic, MD, PhD ([miha.antonc@guest.arnes.si](mailto:miha.antonc@guest.arnes.si)). The data will become available after statistical analysis and public publishment via peer-reviewed article (s). It will be available for all types of analyses.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type                     | Details           | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|-------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | sub-study results | 01/12/2020   | 10/12/2020 | Yes            | No              |
| <a href="#">Results article</a> |                   | 28/05/2022   | 08/06/2022 | Yes            | No              |