ISRCTN98572043 https://doi.org/10.1186/ISRCTN98572043

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

Submission date	Recruitment status	[X] Prospectively registered
02/07/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/11/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/06/2022	Urological and Genital Diseases	

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
Dr Anze Djordjevic

Contact details
Ljubljanska ulica 5
Maribor
Slovenia
2000
+386 (0)40 260 231
anze.djordjevic@ukc-mb.si

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 malondyaldehide concentration in the serum of a subgroup of operated patients. Malondyaldehide 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 malondyaldehide 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 malondyaldehide 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 malondyaldehide 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
Put dr. Goldmana 4
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.antonic@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?
Results article	sub-study results	01/12/2020	10/12/2020	Yes	No
Results article		28/05/2022	08/06/2022	Yes	No