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# Does the use of Microplegia significantly improve outcomes in congenital heart surgery?

**Submission date**
31/05/2016

**Recruitment status**
No longer recruiting

**Registration date**
21/06/2016

**Overall study status**
Completed

**Last Edited**
20/06/2016

**Condition category**
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

## Plain English summary of protocol

Background and study aims
Congenital heart disease is a general term used to describe a range of birth defects that affect the way the heart works. Children with congenital heart disease often need to undergo surgery in order to correct the abnormality that they were born with to improve their chance of survival and quality of life. In order to perform this corrective surgery on the heart, it is necessary to temporarily stop the heart while the defect is repaired. This is usually done by injecting the patient with a solution containing chemicals which temporarily stop the heart (cardioplegia). During this process, it is important that the solutions used protect the heart, preventing injury while it is stopped. The most common solution used is St Thomas II crystalloid cardioplegia (a solution of salts), however in recent years the use of blood cardioplegia, also called microplegia (a mixture of blood with various concentrated additives, such as sotassium) has increased, as it is thought by many to reduce swelling in the heart (myocardial oedema) and allow a quicker recovery of heart function. The aim of this study is to compare the short-term outcomes of using crystalloid cardioplegia and microplegia.

Who can participate?
Children scheduled for corrective congenital heart surgery who way between 5-20 kg.

What does the study involve?
Participants are randomly allocated to one of two groups. For all participants, during surgery the heart is stopped by injecting potassium-rich solutions into the main artery of the heart (aorta). This is at a dose of 30ml/kg initially, with 10ml/kg given repeatedly at 20 minute intervals throughout surgery to maintain the effects. For those in the first group, the cardioplegia given is St Thomas II crystalloid cardioplegia and those in the second group, the cardioplegia given is microplegia. Ice slush is applied around the heart repeatedly throughout surgery in both groups. Before surgery, immediately following the procedure and then six, 12 and 24 hours after surgery, participants have samples of blood taken to test levels of chemicals in the blood related to heart health. Participants are then followed up one week after surgery to evaluate their recovery.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
Charlotte Maxeke Johannesburg Academic Hospital (South Africa)

When is the study starting and how long is it expected to run for?
March 2016 to January 2017

Who is funding the study?
National Research Foundation (South Africa)

Who is the main contact?
1. Dr Sharmel Bhika (public)
2. Dr Krubin Naidoo (scientific)

# Contact information

### Type(s)
Public

### Contact name
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### Type(s)
Scientific

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Dr Krubin Naidoo

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

# Study information

### Scientific Title
A comparison of short-term outcomes between two different cardiac arresting agents in congenital heart surgery: Microplegia Vs St Thomas II crystalloid cardioplegia

### Study objectives
Use of microplegia for myocardial protection results in better early postoperative outcomes compared to crystalloid cardioplegia in congenital heart surgery.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Human Ethics Committee (Medical) of the University of the Witwatersrand, 18/05/2016, ref: M160384

### Study design
Single-centre pilot randomised parallel trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

### Health condition(s) or problem(s) studied
Congenital heart disease

### Interventions
Patients will be randomised to receive either type of cardioplegia solutions, either Microplegia or St Thomas II crystalloid cardioplegia using envelope randomisation.

For all participants, during surgery cardiac arrest will be accomplished by administration of the hyperkalaemic cardioplegia solutions in an antegrade fashion via a cannula which is placed in the ascending aorta, proximal to both the aortic crossclamp and the aortic arterial cannula which perfuses the rest of the body while the heart is arrested. In this way the cardioplegia is directed into the coronary circulation via the coronary artery ostia at the root of the ascending aorta. Further dispersion of the cardioplegia is prevented by a competent aortic valve proximally and the aortic cross clamp distally. The cardioplegia will be delivered at a bolus arresting dose of 30ml/kg and maintenance doses of 10ml/kg given repeatedly at 20 minute intervals at an average aortic root pressure of 80-100mmHg. The volume of these doses for both the cardioplegia solutions being compared will be the same, only the compositions and temperatures differ. Topical ice slush will be applied around the heart repeatedly while maintenance doses of cardioplegia are given throughout the procedure.

The participants will undergo routine postoperative follow up at the referring cardiology clinic. The follow up will include history taking (review of operative note from the surgical team), general examination, cardiac medication review and echocardiographic examination at 1 week post discharge from surgical ward. The patients will continue with routine follow up at the cardiology clinic.

### Intervention Type
Procedure/Surgery

### Primary outcome measure
Lactate, haemoglobin and trophin I levels. The lactate and haemoglobin levels will be measured from arterial blood gases and the troponin I levels will be measured with iStat (Point of care) cartridges at baseline (preoperatively), intraoperatively (following the procedure), 6, 12 and 24 hours postoperatively.

### Secondary outcome measures
1. Postoperative patient fluid balance is measured by recording the balance of fluid (ml) administered to patient and cardiopulmonary bypass machine intraoperatively (from the time the patient enters the operating theatre till the time the patient leaves theatre) against intraoperative fluid losses (urine output + cell-saved blood suctioned intraoperatively)
2. Need for inotropic support postoperatively is measured through use of a classification table immediately postoperatively and at 10am the following morning (one day postoperatively)
3. Need for ventilation postoperatively is measured by recording the number of days that the patient is kept intubated requiring ventilation
4. Systolic and diastolic ventricular function is assessed using echocardiography 2 days postoperatively

### Overall study start date
01/03/2016

### Completion date
31/01/2017

## Eligibility

### Key inclusion criteria
1. Patients scheduled for elective corrective congenital heart surgery with either:
1.1. Tetralogy of Fallot

1.2. Ventricular septal defect
1.3. Atrioventricular septal defects
2. Weight 5-20kg

### Participant type(s)
Patient

### Age group
Child

### Sex
Both

### Target number of participants
80 patients. Pilot study 40 patients.

### Key exclusion criteria
1. Interstitial lung disease
2. Poor preoperative ventricular function EF < 50%
3. Inherent bleeding disorders (e.g. Di George Syndrome, Haemophiliacs, Von Willebrands ds)
4. More than 1 Cardiopulmonary bypass run,
5. Failure to separate from Cardiopulmonary bypass - Extracorporeal Membrane Oxygenation (ECMO), preoperative liver disease
6. Redo surgery

### Date of first enrolment
22/06/2016

### Date of final enrolment
31/10/2016

## Locations

### Countries of recruitment
South Africa

### Study participating centre
**Charlotte Maxeke Johannesburg Academic Hospital**
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## Sponsor information

### Organisation
University of the Witswatersrand Medical Research Department

### Sponsor details
Faculty of Health Sciences, Postgraduate Office
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### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/03rp50x72

## Funder(s)

### Funder type
Not defined

### Funder Name
National Research Foundation

### Alternative Name(s)
South Africa’s National Research Foundation, National Research Foundation (South Africa), NRF

### Funding Body Type
Government organisation

### Funding Body Subtype
Trusts, charities, foundations (both public and private)

### Location
South Africa

## Results and Publications

### Publication and dissemination plan
Planned publication in a peer reviewed journal.

### Intention to publish date

31/01/2018

# Individual participant data (IPD) sharing plan

## IPD sharing plan summary
Available on request