

# The effect of Adenosine on Myocardial Protection in Intermittent warm blood Cardioplegia: a randomized placebo-controlled trial

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Cardiac valve disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON42535

### Source

ToetsingOnline

### Brief title

Adenosine as an adjunct to blood cardioplegia

### Condition

- Cardiac valve disorders

### Synonym

Heart diseases (minimally invasive, port access operations (mitral valve surgery))

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Amphia Ziekenhuis

**Source(s) of monetary or material Support:** Afdeling klinische Farmacie;Amphia ziekenhuis

## Intervention

**Keyword:** adenosine, intermittent warm blood cardioplegia, myocardial protection

## Outcome measures

### Primary outcome

the main study parameter is 6 hours post-operative cTnT.

### Secondary outcome

Secondary outcomes are differences in 18-hour postoperative cTnT levels as determined by the area-under-the-curve (AUC), differences in pre- and post-operative creatine kinase-MB (CK-MB) levels, inotrope usage and dosage, and differences in pre- and postoperative left ventricular ejection fraction (LVEF) and wall motion score index (WMSI) determined by 3-dimensional transesophageal echocardiography (TEE). Furthermore we will compare routine hemodynamic monitoring (i.e. mean arterial pressure, heart rate, cardiac index, and systemic vascular resistance index). Incidence of new onset atrial fibrillation will also be monitored.

## Study description

### Background summary

Myocardial protection is a major issue in cardiac surgery, since inadequate protection increases the risk of postoperative cardiac dysfunction. The main principle of myocardial protection in cardiac surgery is to preserve myocardial function by preventing ischemia with blood cardioplegia . Previous studies have shown that adenosine as an adjunct to blood cardioplegia can be safely used in cardiac surgery. In our institution, adenosine is already used as standard care as an initial cardioplegic bolus in minimally invasive port access operations.

Whether, adenosine as an adjunct to intermittent warm blood cardioplegia, has an added value remains unclear. Therefore we would like to investigate whether the addition of adenosine to standard intermittent warm blood cardioplegia reduces the 6-hours post-operative cardiac troponin T (cTnT) in patients scheduled for minimally invasive, port access operations (mitral valve surgery).

## **Study objective**

The aim of this study is to determine whether the addition of adenosine to standard intermittent warm blood cardioplegia reduces the 6-hours post-operative cTnT in patients scheduled for minimally invasive, port access operations (mitral valve surgery).

## **Study design**

Single center, randomized double-blind placebo-controlled trial.

## **Intervention**

during cardiopulmonary bypass one group receives standard cardioplegic solution (control), the second group receives cardioplegic solution enriched with adenosine (intervention). To maintain cardioplegic arrest, a maintenance dose of cardioplegic solution is given every 20 minutes.

## **Study burden and risks**

As patients are on cardiopulmonary bypass during surgery and biological elimination half-life of adenosine is very short (< 10 seconds), application of adenosine during cardioplegia imposes no increased risk in our patients. The number of blood samples, the number of site visits and other examinations are equal in all groups. No additional tests will be performed as in standard care.

## **Contacts**

### **Public**

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### **Scientific**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

\* Gender; male/ female

\* Age: \* 18 year

\*Elective cardiac surgical patients: - minimally invasive, port-access surgery (mitral valve surgery)

### Exclusion criteria

Other types of cardiac surgery patients

Theophylline or dipyridamole use up to 24 hours prior to surgery

Caffeine use up to 12 hours prior to surgery

Other xanthine derivatives

## Study design

### Design

Study phase: 2

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	04-02-2016
Enrollment:	100
Type:	Actual

## Medical products/devices used

Product type:	Medicine
Brand name:	adenocor
Generic name:	adenosine
Registration:	Yes - NL outside intended use

## Ethics review

Approved WMO	
Date:	28-10-2015
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO	
Date:	16-12-2015
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

## Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
EudraCT	EUCTR 2015-001923-2-NL
CCMO	NL53469.015.15