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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac valve disorders
Study type	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

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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 xantthine 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