# Perioperative esmolol infusion for haemodynamic stability during major vascular surgery.

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Primary Objective: comparing hemodynamic stability provided by titration of esmolol in addition to standard perioperative care including low-dose metoprolol to placebo and standard care.Secondary Objective(s): -comparing the incidence of...

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Coronary artery disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON34500

**Source**
ToetsingOnline

**Brief title**
Perioperative Esmolol Infusion

### Condition

- Coronary artery disorders
- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

**Synonym**
coronary artery disease, sclerosis of the bloodvessels of the heart

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Baxter,Baxter Healthcare Corporation

## Intervention

**Keyword:** esmolol, hemodynamic stability, vascular surgery

## Outcome measures

### Primary outcome

The primary endpoint is hemodynamic stability during the first 24 hours after the start of surgery, where hemodynamic stability is defined as total length of heart rate outside the target window presented in minutes. the target window is defined as a heart rate between 60 and 80 beats per minute.

### Secondary outcome

The key secondary study outcome is the occurrence of myocardial ischemia, defined as either transient electrocardiographic signs of ischemia or Troponin T release or both. In patients with tachycardia and ischemia, the use of rescue medication is considered to be a secondary study endpoint as well, where the dose is noted for every patient. Secondary outcomes also include other safety parameters such as the occurrence of bradycardia (i.e. HR 50 BPM or less) and the occurrence of stroke and transient ischemic attacks (TIA). another secondary outcome measure is 'area under the curve' of episodes of tachycardia.

# Study description

### Background summary

Patients undergoing vascular surgery are likely to have coronary artery disease and are at increased risk of cardiac morbidity and mortality. Perioperative hemodynamic stability is associated with an improved outcome. Beta-blockers can provide hemodynamic stability and reduce the risk of perioperative cardiac

morbidity and mortality in high risk patients. However, a recent study showed an increase in total mortality and stroke. Episodes of hypotension and bradycardia were associated with this increased risk and can be related to high-dose oral long acting beta-blocking agents. Titration of short-acting intravenous esmolol in combination with a low dose of long acting oral beta-blocking agent can achieve hemodynamic stability, while preventing hypotension and bradycardia associated with overdosing of long acting beta-blocking agents.

## Study objective

Primary Objective:
comparing hemodynamic stability provided by titration of esmolol in addition to standard perioperative care including low-dose metoprolol to placebo and standard care.

Secondary Objective(s):
-comparing the incidence of postoperative myocardial ischemia in patients receiving esmolol and standard care versus placebo and standard care.
-comparing safety parameters such as incidence of bradycardia, TIA and stroke in patients receiving esmolol and standard care versus placebo and standard care.

## Study design

STUDY DESIGN

This randomized study compares a group of patients receiving esmolol as an add-on to metoprolol to a group of patients receiving metoprolol plus esmolol placebo . This study compares the combination of metoprolol plus esmolol vs. a mono therapy of metoprolol. patient and research fellow will be blinded, attending anesthesiologist and intensivist are not blinded. The use of a placebo infusion in this study for a total of 24 hours of intra-operative and post-operative periods is only to facilitate blinding. As the influence of concomitant medications, anesthesia, and influence of the surgical procedure, peritoneal traction, on heart rate is recognized, with the use of a placebo, the effect of esmolol in addition to chronic beta-blocker medication can be assessed more objectively.

## Intervention

if at anytime during surgery tachycardia (HR >80 BPM) is present, a bolusinjection of 0.25mg/kg esmolol or placebo is administered, followed by a 25 mcg/kg/min continuous infusion. if this situation does not occur during surgery, a continuous infusion of 25 mcg/kg/min of esmolol or placebo is initiated prior to extubation.

continuous infusion is titrated at 15 minute intervals with 25% of the current dose to maintain a heartrate of 60-80 BPM.

esmolol is not initiated in case of hypotension or bradycardia

**Study burden and risks**

all diagnostic tests and visits to outpatient clinic are part of standard medical care. A recent review described a similar rate of esmolol associated complications such as hypotension and bradycardia for patients treated with esmolol compared to placebo. esmolol or placebo infusion will take place under continuous hemodynamic monitoring and dose will be adjusted to heartrate and bloodpressure. Risks and burden for patients are minimal.

# Contacts

**Public**
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal
3015CE Rotterdam
NL
**Scientific**
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal
3015CE Rotterdam
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

Patients are eligible for inclusion for the study at the Erasmus Medical Centre if they are:
1. Scheduled for arterial vascular surgery, including abdominal aortic aneurysm repair, abdominal aortic stenosis surgery, lower limb arterial reconstruction or carotid artery stenosis repair
2. Provide informed consent

### Exclusion criteria

Potential subjects will be excluded with any of the following:
1. Active bleeding
2. Untreated left main disease
3. Active cardiac condition such as unstable angina pectoris, active congestive heart failure, serious cardiac arrhythmias, symptomatic valvular disease, recent MI< 6 months.
4. Preoperative positive troponin T
5. Contraindication for esmolol use
6. Previous allergy or intolerance to esmolol
7. Cancer with an expected life expectancy < 6 months
8. Excessive alcohol use
9. Pregnancy or planning to become pregnant
10. Failure to provide informed consent
11.Failure to monitor heart rate with the continuous 12-lead electrocardiography because of surgery or baseline electrocardiographic abnormalities.

## Study design

### Design

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|---|---|
| Study phase: | 4 |
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Placebo |
| Primary purpose: | Prevention |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 18-03-2011 |
| Enrollment: | 260 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Brevibloc |
| Generic name: | esmolol |
| Registration: | Yes - NL intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 03-09-2010 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 17-12-2010 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

## Study registrations

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

No registrations found.

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

ID: 20345
Source: Nationaal Trial Register
Title:

## In other registers

| Register | ID |
|---|---|
| EudraCT | EUCTR2010-021844-17-NL |
| CCMO | NL33197.078.10 |
| OMON | NL-OMON20345 |