DECREASE-XIII: A randomized study of perioperative esmolol infusion for haemodynamic stability during major vascular surgery.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20345

Source
Nationaal Trial Register

Brief title
DECREASE-XIII

Health condition

atherosclerosis, vascular surgery, esmolol, cardiac complications

Sponsors and support

Primary sponsor: Erasmus Medical Centre, Rotterdam, The Netherlands
Source(s) of monetary or material Support: Baxter Healthcare Corporation

Intervention

Outcome measures

Primary outcome

Time with a heart rate outside the 60-80 BPM target window during the study drug infusion

period.

Secondary outcome

1. The occurence of cardiac death and myocardial ischemia;

2. Safety parameters such as bradycardia, hypotension, TIA/Stroke.

Study description

Background summary

This study will provide data on the efficacy of esmolol titration in chronic beta-blocker users for tight heart rate control and reduction of ischemia in patients undergoing vascular surgery as well as data on safety parameters.

Study objective

Perioperative esmolol infusion titrated for heart rate control as an add-on to standard therapy including a long acting oral beta-blocker will improve heart rate control and decrease perioperative myocardial ischemia, without an increase in complications as bradycardia, hypotension, heart failure and stroke.

Study design

1. During study drug infusion;

2. Follow-up 30 days.

Intervention

Infusion of esmolol or placebo, initiated during surgery for 24 hours, titrated for a target heart rate of 60-80 BPM, as an add-on to standard therapy including long acting, chronic, oral beta-blocker therapy.

Contacts

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Eligibility criteria

Inclusion criteria

Adult patient undergoing elective major vascular surgery.

Exclusion criteria

1. Bleeding;

2. Unstable cardiac conditions;

3. Contraindications for esmolol use;

4. Failure to provide informed consent;

5. Cancer with life expectancy <6 months;

6. Alcohol abuse;

7. Failure to monitor heart rate and ischemia by continuous 12-lead ECG recording.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-12-2010
Enrollment:	260
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-11-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34500
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2498

Register	ID
NTR-old	NTR2615
CCMO	NL33197.078.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34500

Study results

Summary results
N/A