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Fluvastatin and bisoprolol for the reduction of perioperative cardiac mortality and morbidity in high-risk patients undergoing non-cardiac surgery

Submission date 07/03/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/03/2007	**Overall study status** Completed	
Last Edited 24/11/2011	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR900

Study information

Scientific Title

Acronym
DECREASE IV

Study objectives
The general objective of the DECREASE-IV trial is to assess the clinical efficacy of beta-blocker therapy, statin therapy and combination therapy with beta-blockers and statins in patients undergoing major non-cardiac surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, active controlled, factorial group, multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Non-cardiac surgery, perioperative cardiac complications

Interventions
A computerised version of this scheme will be applied, which enables an automated check on all in- and exclusion criteria. According to the outcome of the risk-evaluation scheme, patients with a chance of more than 2% on perioperative cardiovascular death will undergo further cardiac evaluation, including Electrocardiogram (ECG) and/or stress myocardial testing. Patients with extensive myocardial ischaemia are exluded.

Participants will then be randomised according to an open-label, factorial design between:
1. Beta-blocker therapy (bisoprolol)
2. Statin (fluvastatin)
3. Combination of beta-blockers and statins (bisoprolol and fluvastatin)
4. Neither beta-blockers nor statins (control group)

Study medication is started within zero to 30 days prior to surgery and will be continued until 30 days after surgery.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Fluvastatin and bisoprolol

Primary outcome measure
The primary efficacy objective is to determine the impact of perioperative administration of bisoprolol, fluvastatin and their combination on the incidence of 30-day cardiovascular events, i. e. the composite of cardiac death, and non-fatal Myocardial Infarction (MI), in moderate and high risk patients undergoing non-cardiac surgery.

Secondary outcome measures
1. To determine the impact of perioperative administration of bisoprolol and/or fluvastatin on:
1.1. the incidence of total mortality, cardiovascular death, and non-fatal myocardial infarction during one year follow-up
1.2. the length of hospital stay, and length of Intensive Care Unit (ICU)/Critical Care Unit (CCU) stay
1.3. the 30-day incidence of clinically significant cardiac arrhythmias and heart failure and the need for coronary revascularisation procedures
2. The DECREASE-IV trial has five safety objectives, namely to determine the impact of the different treatments on:
2.1. the 30-day congestive heart failure
2.2. the 30-day incidence of clinically significant bradycardia
2.3. the 30-day incidence of clinically significant hypotension
2.4. the 30-day incidence of clinically significant liver dysfunction
2.5. the occurence of myopathy

Overall study start date
01/07/2004

Completion date
01/07/2008

Eligibility

Key inclusion criteria

1. Aged 40 years or older
2. Scheduled for elective non-cardiac surgery
3. Have an estimated risk for cardiovascular death of more than 1%

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
6000

Key exclusion criteria
1. The use of beta-blockers
2. A contraindication for beta-blocker use
3. The use of statins prior to randomisation
4. A contraindication for statin use
5. Unstable coronary heart disease, evidence of three-vessel disease or left main disease
6. Elevated cholesterol according to the national cholesterol consensus
7. Emergency surgery
8. Inability or unwillingness to provide written informed consent
9. Previous participation in this same trial

Date of first enrolment
01/07/2004

Date of final enrolment
01/07/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Centre
Rotterdam
Netherlands
3015 GD

Sponsor information

Organisation
Erasmus Medical Centre (Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.erasmusmc.nl/

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medical Centre (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2004		Yes	No

Results article	results	01/06/2009	Yes	No