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Perioperative myocardial ischaemia and cytokine response in patients undergoing high-risk surgery: the influence of fluvastatin

Submission date
07/03/2007

Recruitment status
No longer recruiting

Registration date
07/03/2007

Overall study status
Completed

Last Edited
24/11/2011

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR899

Study information

Scientific Title

Acronym
DECREASE III

Study objectives
The primary objective is to study the relation between fluvastatin therapy and the incidence of myocardial ischaemia in patients undergoing high-risk surgery. The secondary objective is to study the perioperative cytokine response in relation to fluvastatin therapy in patients undergoing high-risk surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Medical Ethics Review Committees Erasmus MC (Medische Ethische Toetsings Commissie Erasmus MC) (ref: MEC 238.71/2004/10).

Study design
Randomised double blind placebo controlled parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Perioperative myocardial ischaemia

Interventions
Patients will come for an outpatient visit (= screening) approximately 30 days (= mean) prior to surgery. Informed consent will then be signed and in- and exclusion criteria will be checked. If the patient is eligible for the study, the patient will be randomised and subsequently study medication will be dispensed.

Patients will be randomised to fluvastatin XL 80 mg or placebo once daily from randomisation, approximately one month prior to surgery, to 30 days after surgery. A computer generated random number list will be used to randomise patients. All randomised patients are irrevocably in the study. They will be followed and analysed in the group to which they are allocated, regardless of whether or not they receive the assigned treatment or fulfil the eligibility criteria.

The primary endpoint, myocardial ischaemia, will be measured by continuous 12-lead ECG recording, starting on the evening prior to surgery up to 72 hours after surgery. Furthermore troponin release will be assessed on day one, three, seven after surgery or at discharge.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Fluvastatin

Primary outcome(s)
The primary endpoint is the occurrence of myocardial ischaemia recorded during a 96-hour period using a 12-lead Rozing recorder. Ischaemia is divided into pre-, peri-, and post-operative periods. The severity of ischaemia in each period is scored as 'ischaemic burden', reflecting the duration (minutes) and severity (ST-segment change from baseline) of ischaemia.

Key secondary outcome(s))
1. Perioperative cytokine response. At screening, before the induction of anaesthesia, and after surgery cytokines are measured at six, 24, 48, 72, and 96 hours after surgery; and four, five, six, and seven days after surgery
2. Composite of cardiovascular death and myocardial infarction within 30 days after surgery

Completion date
01/07/2007

Eligibility

Key inclusion criteria
1. Aged greater than 40 years
2. Scheduled for elective noncardiac surgery
3. Risk score for perioperative cardiovascular death greater than or equal to 51 points
5. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Currently on statin therapy
2. Contraindication for statin therapy
3. Scheduled for surgery which interferes with continuous 12-lead Electrocardiogram (ECG) recording, such as thoracic and upper abdominal surgery
4. Unstable coronary disease
5. Undergoing emergency surgery
6. Patients with extensive stress-induced ischaemia during dobutamine stress test
7. Creatine Kinase (CK) at baseline greater than 10 x Upper Limit of Normal (ULN)
8. Previous participation in the fluvastatin-study
9. Reoperation within 30 days of an initial surgical procedure
10. Participation in another clinical trial within the last 30 days

Date of first enrolment
01/07/2004

Date of final enrolment
01/07/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Centre
Rotterdam
Netherlands
3015 GD

Sponsor information

Organisation
Erasmus Medical Centre (Netherlands)

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medical Centre (Netherlands)

Results and Publications

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?
Results article	results	03/09/2009		Yes	No