Perioperative myocardial ischemia and cytokine response in patients undergoing high-risk surgery; the influence of fluvastatin.

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27929

Bron
Nationaal Trial Register

Verkorte titel
DECREASE III

Aandoening

statin; perioperative; vascular surgery; inflammation

Ondersteuning

Primaire sponsor: Erasmus MC, Rotterdam, the Netherlands.
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

This is a randomized, double-blind placebo controlled study evaluating the effect of fluvastatin XL 80 mg on perioperative cardiac ischemic events in patients undergoing major vascular noncardiac surgery. Patients will receive fluvastatin XL 80 mg (n=250) or placebo (n=250) from 30 days prior to surgery up to 30 days after surgery. The primary objective is to study the relation between fluvastatin therapy and the incidence of myocardial ischemia in patients undergoing high-risk surgery. The secondary objective is to study the perioperative cytokine response in relation to fluvastatine therapy in patients undergoing high-risk surgery.

Doel van het onderzoek

The primary objective is to study the relation between fluvastatin therapy and the incidence of myocardial ischemia in patients undergoing high-risk surgery.

The secondary objective is to study the perioperative cytokine response in relation to fluvastatine therapy in patients undergoing high-risk surgery.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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 randomized to fluvastatin XL 80 mg or placebo once daily from randomization, 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 ischemia, 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 1, 3, 7 after surgery or at discharge.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age > 40 years;

2. Scheduled for elective noncardiac surgery;

3. Risk score for perioperative;

4. Cardiovascular death „d51 points;

5. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Currently on statin therapy;

2. Contraindication for statin therapy;

3. Scheduled for surgery which interferes with continuous 12-lead ECG recording, such as thoracic and upper abdominal surgery;

4. Unstable coronary disease;

5. Undergoing emergency surgery;

6. Patients with extensive stress-induced ischemia during dobutamine stress test;

7. CK at baseline > 10x 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind

Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2004
Aantal proefpersonen:	500
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-02-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL884
NTR-old	NTR899
Ander register	: N/A
ISRCTN	ISRCTN83738615

Resultaten

Samenvatting resultaten
N/A