Trial Description

Title

Statin Recapture Therapy before Coronary Artery Bypass Grafting.

Trial Acronym

StaRT-CABG Trial

URL of the trial

http://www.start-cabg.de

Brief Summary in Lay Language

Patients with coronary artery disease requiring coronary artery bypass grafting (CABG) are at risk for postoperative complications after surgery. The StaRT-CABG trial is the first large-scale (2,630 patients) that will investigate whether an additional treatment with statins (lipid-lowering medication) in high doses before CABG surgery can reduce the incidence of major post-surgery complications including death, myocardial infarction and stroke. The StaRT-CABG trial will be recruiting patients from 8 cardiac surgery centres in Germany and is expected to provide relevant clinical data on the efficacy of this novel treatment in order to optimize the care for all patients undergoing CABG.

Brief Summary in Scientific Language

**Patients with coronary artery disease (CAD) requiring coronary artery bypass grafting (CABG) are still at
significant risk for postoperative major adverse cardiocerebral events (≈15% MACCE rate), with ≈3% of
patients dying within 30 days of surgery. Recent clinical evidence shows that cardioprotection in patients
receiving chronic statin treatment can be further improved by a high-dose statin ‘recapture’ therapy given
shortly before an ischemia-reperfusion sequence, resulting in a 61% risk reduction for MACE at 30 days
in patients undergoing PCI. Evaluation of this novel approach in the setting of CABG seems particularly
promising, as myocardial injury, surgery-related inflammation and pre-existing patients’ co-morbidities
play a pivotal role for poor clinical outcomes after CABG that may be improved by an acute statin
recapture therapy. The StaRT-CABG trial is the first large-scale (n=2,630 CABG patients), multicentre (8
cardiac surgery centres), randomised, double-blind and placebo-controlled trial that aims to test whether
an acute high-dose statin recapture therapy given shortly before CABG reduces the incidence of MACCE
at 30 days after surgery (composite primary outcome: all-cause mortality; non-fatal myocardial infarction
and cerebrovascular events). The StaRT-CABG trial is expected to provide highly**

**relevant clinical data on
the efficacy of this novel therapeutic approach in order to optimize the care for all CAD patients
undergoing CABG with broad clinical implications on current clinical practice and existing guidelines.**

Do you plan to share individual participant data with other researchers?

No

Description IPD sharing plan

no

Organizational Data

- DRKS-ID: **DRKS00000753**
- Date of Registration in DRKS: **2012/10/17**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **12-207 , Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**

Secondary IDs

- EudraCT-No.
(for studies acc. to Drug Law): **2011-001795-19**
- BfArM-No.: **4038404**
- Other Secondary-ID: **01KG1103 (BMBF, Förderkennzeichen)**

Health condition or Problem studied

- ICD10: **I25.1 - Atherosclerotic heart disease**

Interventions/Observational Groups

- Arm 1: **Oral statin reload of patients at 12 and 2 hours before CABG using the maximal
dose of the chronically prescribed statin* on admission. (*simvastatin 80 mg, atorvastatin 80 mg, fluvastatin 80 mg or pravastatin 40 mg)**
- Arm 2: **Placebo given orally 12 hrs and 2 hrs before CABG**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist, caregiver, assessor, data analyst**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary efficacy endpoint:
Major adverse cardiocerebral events (MACCE) within 30 days after CABG.
Composite endpoint consisting of:
(1) all-cause mortality, (2) non-fatal myocardial infarction (MI) and (3) non-fatal cerebrovascular event (stroke or TIA)

Secondary Outcome

1. Major adverse cardiac events: cardiac mortality and non-fatal MI within 30 days
2. New-onset atrial fibrillation
3. Postoperative enzymatic myocardial injury (troponin T, CK-MB)
4. Length of stay on intensive care unit (ICU) and hospital
5. Repeat coronary revascularisation
6. All-cause mortality at 12 months

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Herz- und Throaxchirurgie, Köln**

Recruitment

- Planned/Actual: **Actual**

Planned/Actual: **Actual**

- (Anticipated or Actual) Date of First Enrollment: **2012/11/07**
- Target Sample Size: **2630**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Key inclusion criteria:
1. Patients on chronic statin treatment (>30 days) scheduled for isolated CABG, including on- or off-pump or repeat (redo's) revascularisation procedures
2. Stable or unstable angina, including non ST-segment-elevation acute coronary syndrome (NSTE-ACS)
3. Age ≥ 18 years
4. Written informed consent

Exclusion criteria

Key exclusion criteria:
1. Any concomitant cardiovascular procedure to CABG (i.e. valve, aortic or carotid surgery)
2. Acute ST-segment-elevation myocardial infarction (STEMI)
3. NSTE-ACS with cardiogenic shock warranting emergent salvage surgery within 12 hrs from hospital admission
4. History of atrial fibrillation or muscle disease (myopathy)
5. Current renal (creatinine>2x ULN, dialysis, kidney transplant) or hepatic dysfunction (AST/ALT>2x ULN, liver transplant or neoplasm)
6. Inability of oral drug intake

Addresses

- **Primary Sponsor**

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■ **Contact for Scientific Queries**

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- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2020/05/01**

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*