

HYbrid-Revascularisation In Senescent Cohorts: a prospective randomised comparative trial between minimally-invasive coronary revascularisation treatment without extra- corporeal circulation (off pump coronary surgery) and combined stent-implantation versus conventionally surgical treatment in cardioplegia with the aid of extra-corporeal circulation

Submission date 05/01/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 13/02/2007	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 13/02/2007	Condition category Circulatory System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ivar Friedrich

Contact details
Universitätsklinik und Poliklinik für Herz- und Thoraxchirurgie
Ernst-Grube-Straße 40
Halle/Saale
Germany
06097
ivar.friedrich@medizin.uni-halle.de

Additional identifiers

Protocol serial number

KKSH-018/1

Study information

Scientific Title

Acronym

HYRISC

Study objectives

A decrease of postoperative rate of complications by hybrid-revascularisation is expected.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Medical Faculty of the Martin-Luther-University Halle-Wittenberg, approval received on 23/02/2005.

Primary study design

Interventional

Study design

Open-label, randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Multi-vessel coronary heart disease with diseased LAD requiring surgery

Interventions

1. Hybrid group: surgical revascularisation of LAD with left Arteria thoracica interna-Bypass supply of dominant not interventional treatable vessels by off-pump technique.
2. Conventionally treated group: surgical revascularisation in cardioplegia by use of heart-lung machine.
3. Consecutive observed control group: surgical revascularisation in cardioplegia by use of heart-lung machine.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Occurrence of post-operative complications (organ insufficiencies, stroke, myocardial infarction, symptomatic transitory psychotic syndrome, infection, shock, multiple systems organ failure, death) during hospitalisation.

Key secondary outcome(s)

1. Lethality and therapy costs during hospitalisation and in the first post-operative year
2. Survival after six and 12 month
3. Rates of complications (see primary outcomes)
4. Post-operative quality of life (Short Form health survey [SF-36], Hospital Anxiety and Depression Scale [HADS])
5. Occurrence of postoperative complications in the group of consecutive observed younger patients (control group)

Completion date

30/09/2007

Eligibility

Key inclusion criteria

1. Coronary heart disease with diseased Left Anterior Descending coronary artery (LAD) requiring surgery
2. Male or female patients with 75 years of age or older in therapy groups
3. Male or female patients with 60 years of age or less in consecutive observed younger patients (control group)
4. Signed and dated informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Key exclusion criteria

1. Combined surgery (heart valve plus bypass)
2. Emergency treatment along with unstable cardiovascular system
3. Known intolerability of AcetylSalicylic acid (ASS), Clopidogrel and other concomitant medication required for stent-implantation
4. Participation on other clinical trials
5. Situations that limit the compliance with study requirements

Date of first enrolment

10/06/2005

Date of final enrolment

30/09/2007

Locations

Countries of recruitment

Germany

Study participating centre

Universitätsklinik und Poliklinik für Herz- und Thoraxchirurgie

Halle/Saale

Germany

06097

Sponsor information

Organisation

Martin Luther-University Halle-Wittenberg (Germany)

ROR

<https://ror.org/05gqaka33>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Self-funded by the Department of Cardiothoracic Surgery and Cardiology, Martin-Luther-University Halle (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration