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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

Registration date
13/02/2007

Overall study status
Completed

Last Edited
13/02/2007

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

Study design
Open-label, randomised controlled 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
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 measure
Occurrence of post-operative complications (organ insufficiencies, stroke, myocardial infarction, symptomatic transitory psychotic syndrome, infection, shock, multiple systems organ failure, death) during hospitalisation.

Secondary outcome measures
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)

Overall study start date
10/06/2005

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

Age group
Not Specified

Sex

Both

Target number of participants
459

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)

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

Sponsor type
Hospital/treatment centre

Website
http://www2.uni-halle.de/index_e.htm

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

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