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

	Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Circulatory System	Record updated in last year
	Completed Condition category

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

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