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Clinical comparison between a manual suture and a sutureless coupling device (corVCD) connecting the subclavian artery with a 4-finger graft in a complete aortic arch replacement

Submission date 12/09/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/09/2013	**Overall study status** Completed	
Last Edited 20/08/2018	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
The vascular coupling device (corVCD) is a non-active long-term implant made of nitinol. It can be used for the fast and effective anastomosis (surgical connection) of an artery to a vascular prosthesis and replaces the conventional technique, a circumferential suture.
In this study corVCD will connect one branch of an aortic arch prosthesis with the left subclavian artery, which is used in patients with the need for an artificial aortic arch replacement. The aim is to reduce the circulatory arrest time (a surgical technique involving cooling the body of the patient and stopping blood circulation) for the patients and minimize the occurrence of adverse events.

Who can participate?
Elective patients, men and women between 18 and 80 years, suffering from chronic aortic dissections or aneurysms with the indication for an aortic arch replacement.

What does the study involve?
For this study the patient population will be randomly allocated to one of two groups:
Group 1: the surgery will be performed using the conventional technique, a circumferential suture.
Group 2: the surgery will be performed with the corVCD.
Follow-up care is carried out at discharge from hospital and after 3 and 6 months. The final investigation takes place after 12 months.

What are the possible benefits and risks of participating?
The use of corVCD could shorten the time for the anastomosis of the left subclavian artery and therefore the overall circulatory arrest time. The circulatory arrest is high-risk but necessary in the replacement of the aortic arch. This procedure may reduce side effects like brain disorders.
The application of corVCD can lead to undesired effects or discomfort like:
-Dissections due to the introduction of corVCD in the artery

-Bleedings caused by migration of the corVCD
-Thrombosis/embolism caused by blood clots
-Gradual narrowing of arm supplying vessel
-Fever and pain because of local inflammation
All of these complications could extend the treatment or make a new surgery necessary.

Where is the study run from?
Hannover Medical School in Germany.

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start in October 2013. Participants will be enrolled on the study for a period of 2 years. The follow-up examinations extend over 1 year, so the approximate duration of the trial is 3 years.

Who is funding the study?
Funding has been provided by the Corlife oHG, Germany.

Who is the main contact?
Nicolin Heister, study coordinator, nicolin.heister@corlife.eu
Carmen Puschmann, carmen.puschmann@corlife.eu

Contact information

Type(s)
Scientific

Contact name
Prof Malakh Lal Shrestha

Contact details
Medizinische Hochschule Hannover
Herz- Thorax- Transplantations- Gefaesschirurgie
Carl-Neuberg-Str. 1
Hannover
Germany
30625

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
CLinical comparison bEtween a manual suture and a sutureless coupling device (cOrVCD) coNnecting the subclavian Artery with a 4-finger graft in a complete aortic arch replacement: a RanDOmized controlled study

Acronym
LEONARDO

Study objectives
The primary goal of this study is to lower the circulatory arrest time required for the implantation of an aortic arch prosthesis.

Secondary goals are to shorten the time for the anastomosis of the left subclavian artery to an aortic arch prosthesis and to reduce adverse events (AE) and serious adverse events (SAE) until 12 month after implantation.

Null hypothesis: The circulatory arrest time required for the implantation of an aortic arch prosthesis is equal for the use of conventional suture and the use of corVCD.

Alternative hypothesis: The corVCD vascular coupling allows a significant reduction of the circulatory arrest time.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Hannover Medical School, 21/08/2013, ref #: 6430 MPG-LKP mono

Study design
Interventional prospective randomized open single center trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Vascular diseases like chronic dissections or aneurysms in the area of the aortic arch and the supra-aortic vessels

Interventions
The aortic arch prosthesis is surgically implanted via a sternotomy under general anesthesia. Initially the aortic arch with its supra-aortic vessels are prepared.
The aortic arch prosthesis is made of dacron and has three branches for the connection of the three diverging arteries (Truncus brachiocephalicus, Arteria carotis communis sinistra and Arteria subclavia sinistra).
The prosthesis is implanted conventionally. The first two supra-aortic arteries, Truncus brachiocephalicus and Arteria carotis communis sinistra, are sutured circumferentially in a conventional handmade end-to-end technique with the prosthesis.
Only the connection of the left subclavian artery to the aortic arch prosthesis in performed differently in the two trial arms:

Trial arm 1: Conventional anastomosis: In these cases the connection of the prosthesis to the left subclavian artery is carried out by conventional end-to-end suture anastomosis.
Trial arm 2: Vascular coupling corVCD: The vascular coupling device is inserted in the prosthesis with the applicator corCAP and fixed with one or two security stitches. It should be noted that the weld is carried out in a longitudinal direction to fix one of the outer rings of corVCD to the prosthesis. Afterwards the left subclavian artery is pulled over the prosthesis, while the coupling is held in position by the applicator. In the middle of the sandwich (corVCD, prosthesis, vessel) the ligation is carried out with at least two overhand knots by using non-absorbable suture. Then the applicator is retracted out of the prosthesis.
The connection of the hybrid graft to the descending and ascending aorta by conventional suture technique is common in two groups. Subsequently, the blood flow and therefore the perfusion of the supra-aortic vessels can be released. The vessels are checked for leaks. For the final control of adequate positioning pulse checks are carried out in both arms.

Follow-up care is carried out at discharge from hospital and after 3 and 6 months. The final investigation takes place after 12 months. Following parameters are examined:
1. Query to newly emerging and existing diseases as well as new or modified concurrent medication
2. Clinical examination
3. Haemogram
4. Vital signs (blood pressure, pulse measuring)
5. Computerised tomography (not at follow-up after 3 and 6 month)
Further observation of patients after study closure is carried out based on the ACCF/AHA guideline for the diagnosis and management of patients with thoracic aortic disease.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
The circulatory arrest time of 30± 10 min should be reduced to 20±10 min by the use of corVCD. The verification takes place by time recording.

Secondary outcome measures
1. With the use of corVCD the time needed to reach a blood-dry anastomosis of the left subclavian artery should be reduced contrary to the application of a conventional suture. The verification takes place by time recording.

2. Potential occurring adverse events (AE) and serious adverse events (SAE) should be less by the use of corVCD in a period of 12 months after surgery.

Overall study start date
01/10/2013

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Patients with aneurysms (aortic caliber ≥5.5 cm) or chronic dissections in the area of the aortic arch with indication of an open surgery with an aortic arch prosthesis regarding ACCF/AHA guideline.
2. Patient suitable for operation
3. The patient has opted for an open surgery after deliberating about different available procedures
4. An inner diameter of the Arteria subclavia sinistra of 6.1 to 12.5 mm
5. Serum creatinine ≤ 1.8 mg/dl
6. Estimated life expectancy > 5 years
7. Patient aged 18 to 80 years
8. Written consent form for study participation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Patient cannot undergo an open surgery with circulatory arrest
2. Acute aortic dissection
3. Previous radiation treatment of the target region
4. Local or systemic infections
5. Pre-terminal renal insufficiency (serum creatinine > 1.8 mg/dl) or contrast agent intolerance
6. Conditions in the target region which inhibit an application of prosthetic material
7. Any other life-limiting disease (with an estimated life expectancy < 5 years)
8. Patient age ≤ 18 or ≥ 80 years
9. Pregnancy or lactation
10. Any other disease or medical treatment which interferes with safety or efficacy after

assessment of the investigator
11. Patients who are in a dependency relationship or employment with the sponsor or investigator
12. Patients who are unable to give written consent for study participation
13. Concurrent participation in another clinical study
14. Hypersensitivity or allergy against nickel or titanium
15. Hypersensitivity against suture material
16. Absence of a written consent form for study participation

Date of first enrolment
01/10/2013

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
Germany

Study participating centre
Medizinische Hochschule Hannover
Hannover
Germany
30625

Sponsor information

Organisation
Corlife OHG (Germany)

Sponsor details
Feodor-Lynen-Str. 23
Hannover
Germany
30625

Sponsor type
Industry

Website
http://www.corlife.eu

ROR
https://ror.org/03vsz6k78

Funder(s)

Funder type
Industry

Funder Name
Corlife OHG (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