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

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

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

- 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.

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 quideline.
- 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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 \leq 18 or \geq 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)

ROR

https://ror.org/03vsz6k78

Funder(s)

Funder type

Industry

Funder Name

Corlife OHG (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type **Details** Date created Date added Peer reviewed? Patient-facing? Participant information sheet 11/11/2025 11/11/2025 No

Participant information sheet

Yes