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Endovascular treatment of aortic arch chronic dissection with a branched endograft following previous ascending aorta replacement for Acute Type A dissection: midterm results from an international multicenter study

Submission date
10/04/2018

Recruitment status
No longer recruiting

Registration date
11/06/2018

Overall study status
Completed

Last Edited
23/04/2019

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Acute aortic dissection is a disease with a risk of rupture of the ascending aorta (the part of the aorta after the heart) that can be treated with prosthetic replacement of the ascending aorta. After the repair and during follow up of those patients, the residual part of the aorta (the aortic arch) can heal with time. In other cases, the remaining persistent dissected part of the aorta can grow in diameter leading to an aneurysm (bulge). In this case, there is a risk of rupture of the aneurysm causing the death of the patient. The only way to prevent this rupture is a preventive surgery of the dilated part of the aorta. The conventional treatment for those aneurysms is a surgical replacement of the aortic arch. This surgery has high mortality and morbidity rates. This surgery is performed under general anaesthesia and requires extracorporeal circulation (circulation of blood outside the body through a machine) with hypothermic circulatory arrest (temporarily stopping blood flow under very cold body temperatures). Only healthy patients can undergo this surgery. Recently, a group of surgeons have used an endovascular approach for degenerative aneurysm of the aortic arch (non dissecting aneurysms). The device used is a long covered stent (tube) with two branches to keep supra aortic vessels (for the brain and the arms) patent (open). This device is custom made for each patient's anatomy. This technique had acceptable mortality and morbidity rates. The encouraging results of the early experience with this device have led to the use of this technique in chronic dissection of the aortic arch. The aim of this study is to assess the results of this endovascular treatment of dissecting aneurysm of the aortic arch in patients previously treated for an acute aortic dissection.

Who can participate?
Patients aged 18 or older previously treated for an acute aortic dissection with a custom-made branched endograft

What does the study involve?
Data about patients treated with this device around the world are collected and analysed. Rates of in-hospital mortality and stroke, technical success, early and late complications, re-intervention, and mortality during follow-up are evaluated.

What are the possible benefits and risks of participating?
There are no benefits and risks for participating patients in this study. Patients would have the same surgical repair with or without recruitment into this study. The benefits of this endovascular repair are low mortality and stroke rates in the short term. The risk of this endovascular approach is a high late re-intervention rate.

Where is the study run from?
1. Centre Chirurgical Marie Lannelongue
2. University Hospital Eppendorf
3. CHU de Lille
4. Skane University Hospital
5. Uppsala University Hospital
6. Cleveland Clinic
7. Serviço Integrado de Técnicas Endovasculares
8. Maastricht University Medical Center
9. St Thomas' Hospital
10. University Medical Center Regensburg
11. Queen Elizabeth University Hospital NHS Foundation Trust
12. Queen Mary Hospital
13. CHU de Nantes
14. Medical University of Warsaw

When is the study starting and how long is it expected to run for?
December 2017 to September 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dorian Verscheure
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
063290

Study information

Scientific Title
Endovascular treatment of aortic arch chronic dissection with a branched endograft following previous ascending aorta replacement for Acute Type A dissection: midterm results from an international multicenter study

Study objectives
Endovascular treatment of aortic arch chronic dissection with a branched endograft following previous ascending aorta replacement for Acute Type A dissection is a safe and efficient method.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comité d'Ethique de Recherche Clinique de la Société Française de Chirurgie Thoracique et Cardio-Vasculaire (Ethical committee in clinical research of the French society of thoracic and cardiovascular surgery), 22/04/2018, ref: CERC-SFCTCV-2018-3-7-20-50-27-vedo

Study design
Retrospective multicentre international observational study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied
Aortic arch chronic dissection following ascending aorta prosthetic replacement for acute Stanford A dissection

Interventions
Endovascular repair of aortic arch chronic dissection with a custom made branched endograft (Cook Medical, Bloomington, In, USA).
Endografts includes 2 branched (one for the brachiocephalic trunk and one for the left common carotid artery (LCC), requiring left subclavian artery (LSA) transposition or bypass) or 3 branched (one for each supra aortic trunk) devices.
In order to deliver the components, three arterial access sites are required:
1. Femoral access to insert the endograft over a stiff wire positioned through the aortic valve into the left ventricle.
2. Right common carotid or right axillary access to catheterize the innominate internal side branch and to insert the covered stent bridging the branch to the IT.
3. Left axillary or brachial access to catheterize the LCC through the LSA transposition or bypass, and the LCC internal side branch to deliver the covered stent bridging the side branch to the LCC.
After systemic heparinization with 100 IU/kg (target activated clotting time [ACT] > 300 seconds), catheters and/or sheaths are placed to mark the origins of the innominate artery and LCC or LSA, a catheter is positioned close to the apex of the left ventricle from the femoral access and a stiff wire (Lunderquist, Cook Medical) is advanced through this catheter. The position of the tip of the stiff wire is constantly visualized. Under fluoroscopy, the graft is verified outside the patient to get accustomed to the numerous radio-opaque markers and then delivered over the stiff wire to the aortic arch. The tapered short tip is brought through the aortic valve, into the left ventricle. An angiogram is performed. If the branches along with their associated markers are positioned adequately, the graft is deployed under cardiac output reduction using rapid pacing, inferior vena cava occlusion or pharmacologic cardiac arrest. Normal cardiac output is resumed prior to withdrawing the tapered tip of the delivery system and the stiff wire from the left ventricle. The side branches are catheterized from the target vessels and sheaths are positioned into the inner side branches. Appropriate bridging limbs and covered stents are advanced through the access sheaths into the target vessels and deployed. On table angiography completes the procedure to confirm complete exclusion of the aneurysm and patency of the branches.

The trialists will measure: in hospital stroke and mortality rates, technical success of the surgical procedure, in hospital complications (cardiac, renal and respiratory failure, reinterventions), late complications (stroke, reintervention, aortic related complications) and mortality rate. There is no maximal follow up, the trialists use the most recent data for each patient.

Intervention Type
Procedure/Surgery

Primary outcome measure
Rates of in-hospital mortality and stroke, measured during the postoperative course (between surgical procedure and postoperative day 30)

Secondary outcome measures

1. Technical success, defined as successful delivery of the endograft without type 1 endoleak and evaluated on the preoperative angiogram, without death during the first 24 postoperative hours. Measured during the beginning of the surgical procedure and postoperative hour 24
2. Early complications, measured using evaluation of the presence of cardiac (troponin elevation with electrocardiogram modification), renal (elevation of creatinin level requiring extracorporeal epuration) or respiratory (hypoxemia, pneumoniae or reintubation) failure or necessity of secondary surgical procedure. Measured before postoperative day 30
3. Late complications, measured using the same measurement as early complications
4. Re-intervention and mortality rates measured during follow up (between postoperative day 30 and the most recent news)

Overall study start date
02/12/2017

Completion date
25/09/2018

Eligibility

Key inclusion criteria
1. Patients aged 18 or older
2. With prior ascending aorta prosthetic replacement for Stanford A acute dissection
3. With chronic dissection of the aortic arch with arch dilatation
4. Treated with a custom-made branched endograft (Cook Medical, Bloomington, In, USA)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
70

Total final enrolment
70

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
02/12/2017

Date of final enrolment
01/04/2018

Locations

Countries of recruitment
Brazil

England

France

Germany

Hong Kong

Netherlands

Poland

Sweden

United Kingdom

United States of America

Study participating centre
Centre Chirurgical Marie Lannelongue
133 avenue de la résistance
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Study participating centre
University Hospital Eppendorf
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Study participating centre
CHU de Lille
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Study participating centre
Skane University Hospital
Sweden
214 28

Study participating centre
Uppsala University Hospital
Sweden
751 85

Study participating centre
Cleveland Clinic
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Sponsor information

Organisation
Centre Chirurgical Marie Lannelongue

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/029gxzx35

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The trialists plan to publish their results in Circulation around August 2018

Intention to publish date
01/08/2018

Individual participant data (IPD) sharing plan
Datas can be available later and will be held in a secure computer in the trialists' institution

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2021		Yes	No