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Creating a registry of data of patients who have undergone endovascular reconstruction for aortic occlusive disease to assess treatment outcomes

Submission date
29/04/2020

Recruitment status
No longer recruiting

Registration date
05/05/2020

Overall study status
Completed

Last Edited
05/05/2020

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Narrowing or blockages in the major arteries (aorto-iliac occlusive disease) can cause reduced blood flow to areas of the body leading to symptoms of pain (especially on movement) and tissue death (gangrene).

This is currently treated in Europe primarily using keyhole surgery techniques. These techniques are referred to as endovascular surgery. This may involve inserting a stent to keep the artery open for sufficient blood flow. The patient outcomes of these new techniques in treating blocked major arteries in the body are not well known.

Covered Endovascular Reconstruction of Aortic Bifurcation (CERAB) is a technique described to treat extensive aorto-iliac occlusive disease, especially in high risk patients. Despite promising outcomes from three years of research in cohorts from single hospitals, there is a lack of published results from other centres being able to reproduce these outcomes of this technique. Additionally, there are not currently results comparing the use of stent grafts (covered stents) and Bare Metal Stenting (BMS) for the endovascular treatment of aorto-iliac disease.

This study will look at the fate of patients who had this kind of treatment in many centres across Europe. The study aims to provide an understanding of what problems patients face following the surgeries and how optimal treatment can be provided.

Who can participate?
Information will be collected from patients who received treatment for aorto-iliac occlusive disease using endovascular surgery.

What does the study involve?
This is an observational trial. Patients will receive standard clinical care as per local policies and physicians' preference, and will not be required to attend any additional follow-up beyond standard care.

What are the possible benefits and risks of participating?
Only patients who have already had their surgery will be reported as part of this study. This project will have absolutely no impact on the clinical care of patients. No identifiable information will be collected and reported. There are no risks of participating as essentially the clinical care remains exactly the same.

Where is the study run from?
1. Guy's and St Thomas' NHS Foundation Trust (UK)
2. Leicester Vascular Institute (UK)
3. St Franziskus Hospital Münster (German)

When is the study starting and how long is it expected to run for?
Information for patients who had their surgery from May 2016 to April 2020 will be collected and reported

Who is funding the study?
This study is investigator-initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
COBRA_01

Study information

Scientific Title
Covered Stents vs Bare Metal Stent Endovascular Reconstruction for Aortic Occlusive Disease (COBRA registry)

Acronym
COBRA Registry

Study objectives
To describe the short and medium-term outcomes following Covered Endovascular Reconstruction of Aortic Bifurcation (CERAB) and compare these with the performance of Bare Metal Stenting (BMS) reconstructions in a multicentre registry.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. NHS ethics approval not required as per HRA opinion March 2020, this registry does not impact on the pathway of clinical care and no identifiable data are collected. This is an observational study. Each centre outside the United Kingdom should seek all relevant approvals as per their local/national policies before commencing data collection of any description.
2. Ethical approval will be sought locally in Germany (St. Franziskus Hospital in Muenster) but this had been delayed due to the current public health emergency.

Study design
International multicentre cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Aortoiliac steno-occlusive arterial disease with ischaemic pain at rest or when walking (claudication) or tissue loss (gangrene)

Interventions
This is an observational trial using retrospective data. Patients will receive standard clinical care as per best available evidence, local/regional/national care pathways, and physicians' preference using CERAB/endovascular treatment of aorto-iliac disease using a combination of covered stents and BMS in the aorta. Patients will not have any additional follow up, assessment or reporting to the investigators beyond standard clinical care. The surgical techniques and stents used, as well as patient outcome data, will be collected from clinician notes. No patient identifiable data will be collected or communicated.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
A variety of BMSs and covered stents may be used as per local policies and physicians' preferences.

Primary outcome measure
Re-intervention-free-survival, defined as the composite endpoint of target lesion revascularization (TLR) and/or death, whichever occurred first, obtained from clinician notes collected at day of discharge from hospital, 30 days after the procedure, and latest available follow-up.

Secondary outcome measures
The following outcome measures will be obtained from clinician notes, collected at day of discharge from hospital, 30 days after the procedure, and latest available follow-up
1. Acute technical success
2. 30-days morbidity
3. 30-days mortality
4. Overall mortality
5. Conversion-to-surgery free time
6. Re-intervention free time

Overall study start date
01/02/2020

Completion date
30/04/2021

Eligibility

Key inclusion criteria
1. Infrarenal chronic aorto-iliac occlusive/stenotic symptomatic disease for >14 Days
2. Treatment by an aortic stent graft or bare metal stent with or without iliac stenting

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Observational study - no actual target.

Key exclusion criteria
1. Acute aortic occlusive disease
2. Aneurysm related interventions
3. Previous aorto-iliac stenting or In-Stent-Restenosis
4. Aortic coarctation
5. Isolated Kissing-Stent-Reconstruction without aortic stents
6. Aortic injury/trauma related interventions
7. Suprarenal/visceral segment reconstructions

Date of first enrolment
01/05/2016

Date of final enrolment
30/04/2020

Locations

Countries of recruitment
Belgium

England

France

Germany

Greece

Italy

Netherlands

Spain

United Kingdom

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
Vascular Surgery Department
St Thomas' Hospital
Westminster Road, 1st floor
London
United Kingdom
SE1 7EH

Study participating centre
St Franziskus Hospital Münster
Department of Vascular Surgery
Hohenzollernring 70
Münster
Germany
48145

Study participating centre
Leicester Vascular Institute
Glenfield Hospital
Groby Road
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United Kingdom
LR3 9QP

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust

Sponsor details
St Thomas' Hospital
Vascular Surgery Department North Wing
Westminster Bridge Road
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SE1 7EH
+44 02071887188
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Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/Home.aspx

ROR
https://ror.org/00j161312

Organisation
St. Franziskus Hospital

Sponsor details
Hohenzollernring 70
Münster
Germany
48145
+49 0251 9350
stavroulakis.konstantinos@yahoo.gr

Sponsor type
Hospital/treatment centre

Website
http://www.sfh-muenster.de/uk/home.html

ROR
https://ror.org/051nxfa23

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Publication and dissemination intended in peer-reviewed journal, conferences, and online media.

Intention to publish date

30/01/2023

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Not expected to be made available