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British Orbital Atherectomy Registry

Submission date
20/12/2024

Recruitment status
Recruiting

Registration date
23/12/2024

Overall study status
Ongoing

Last Edited
02/07/2025

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Heart attacks are caused by coronary artery disease and despite improvements in treatment, this is still a common cause of death in both the UK and internationally. Due to advances in medical care and lifestyle modifications, populations are ageing. This means that patients are developing more complex coronary artery disease, specifically calcium within the blood vessels. This calcium is difficult to treat and historically has resulted in worse outcomes when treated with stents (small metallic scaffolds that hold the heart arteries open). Several devices are available to help disrupt calcium in the heart arteries, orbital atherectomy being one of them that is particularly useful for the more complex calcium within heart arteries. Most stent procedures are performed with x-ray guidance only but there is a wealth of evidence and guidelines now support the use of internal imaging cameras to help optimise stent results. The imaging camera with the best resolution is called optical coherence tomography. Both orbital atherectomy and optical coherence tomography are in routine clinical use within the UK. This study aims to evaluate the effectiveness of orbital atherectomy used for complex coronary calcification with optical coherence tomography. This will help those clinicians using the devices to potentially improve the management of future patients with this condition.

Who can participate?
Adult (>18 years of age) patients who have a specific type of complex calcified coronary artery disease and are treated with orbital atherectomy using optical coherence tomography using a strategy that is considered optimal based on previous evidence and guidelines.

What does the study involve?
This is an observational registry and therefore the study does not result in any changes in the management of participants. It involves the collection of data specifically relevant to the study aims, review of the x-ray and optical coherence tomography by specialised experts (in an anonymous fashion) and follow-up at one year following the stenting procedure.

What are the possible benefits and risks of participating in the study?
This is a registry so there are no additional risks to patients from participating in the study. Participants included in the study will already have had treatment of complex coronary artery calcium using orbital atherectomy and optical coherence tomography in an optimal strategy. There are no specific benefits to participants themselves but this study will help to inform clinicians on the management of similar patients in the future.

Where is the study run from?
The study will be conducted in the UK in up to 20 sites with a broad experience of both devices. The study will be run by University Hospital Dorset, Bournemouth, UK.

When is the study starting and how long is it expected to run for?
January 2024 to January 2030. The aim is to recruit the first participant in June 2024. Recruitment will continue for three years unless 300 participants have been recruited in which case recruitment will finish early. There is a one-year follow-up after recruitment and therefore the results will be anticipated to be available 18 months after the final participant recruitment.

Who is funding the study?
Abbott Vascular

Who is the main study contact?
Ms Sarah Savage, sarah.savage@uhd.nhs.uk

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Additional identifiers

Integrated Research Application System (IRAS)
356586

Study information

Scientific Title
British Orbital Atherectomy Registry (retrospective and prospective)

Acronym
BOAR

Study objectives
This is an observational study to assess the real-world outcomes of orbital atherectomy in complex coronary calcification

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/06/2025, Greater Manchester Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8084; gmcentral.rec@hra.nhs.uk), ref: 25/NW/0153

Primary study design
Observational

Study design
Prospective observational study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ischaemic heart disease, specifically complex coronary calcification

Interventions
This is an observational study of patients treated with orbital atherectomy with optical coherence tomography for complex coronary calcification. The use of orbital atherectomy is routine practice and the combination with optical coherence tomography (or any intracoronary imaging) is recommended within international guidelines. This registry will follow up with patients treated for complex coronary calcification who are treated as part of routine practice using these techniques.

Intervention Type
Other

Primary outcome(s)
Target vessel failure (TVF) at one year, a composite of cardiac death, target vessel revascularization (TVR), and target vessel myocardial infarction (TVMI), measured using data collected in patient medical records at one timepoint

Key secondary outcome(s)
The following secondary outcome measures are assessed using data collected in patient medical records at one timepoint:
1. Cardiac death, TVMI, TVR at one year
2. Presence of procedural complications
3. Residual angiographic stenosis <50%
4. Optical coherence tomography expansion index, minimal stent area, presence of edge dissections, eccentricity index, presence of malposition
5. Impact of orbital atherectomy and any other calcium modification device utilised on calcium (volume reduction, presence of fractures)
6. Procedural duration, change in management strategy with orbital atherectomy/optical coherence tomography

Completion date
01/01/2030

Eligibility

Key inclusion criteria
1. Age 18 years or over
2. Orbital atherectomy usage, or attempted orbital atherectomy for coronary calcification felt to be significant (whether that be based on a fluoroscopic or optical coherence tomography assessment) by the supervising interventional cardiologist and meeting one of the following entry criteria: non-crossable calcification; Fujino optical coherence tomography calcification score of 4; balloon undilatable lesion.
3. Patient willing to be included in the registry
4. Intended optical coherence tomography-guided percutaneous coronary intervention (minimum of two attempted runs: postorbital atherectomy and final run post stent

optimization).
5. In addition, where optical coherence tomography will cross the lesion, a run will be performed pre-orbital atherectomy (to characterise the calcium morphology and volume)
6. An optical coherence tomography run is mandated following any other calcium modification strategy utilized (to evaluate whether the additional modification demonstrates a significant additional modification of the calcium on optical coherence tomography)
7. Planned use of Xience stents
8. Denovo disease
9. Declared PCI strategy (planned direct viper wire of vessel, need for intravascular lithotripsy /speciality balloons and stent strategy) prior to percutaneous coronary intervention procedure

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Pregnant or breastfeeding
2. Unable to give informed consent
3. percutaneous coronary intervention performed without optical coherence tomography attempt
4. No orbital atherectomy use
5. Planned treatment of a lesion that includes an area previously treated with a stent
6. Treatment of a bypass graft
7. PCI within the preceding 30 days

Date of first enrolment
01/08/2025

Date of final enrolment
01/06/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals Dorset - Royal Bournemouth Hospital
Castle Lane East
Bournemouth
United Kingdom
BH7 7DW

Study participating centre
Other centres yet to be confirmed (upto 20 UK sites)
United Kingdom
bh77dw

Sponsor information

Organisation
University Hospitals Dorset NHS Foundation Trust

ROR
https://ror.org/02pa0cy79

Funder(s)

Funder type
Industry

Funder Name
Abbott Vascular

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

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

Data sharing statement to be made available at a later date