

British Orbital Atherectomy Registry

Submission date 20/12/2024	Recruitment status Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/12/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/12/2024	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English Summary

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

Contact information

Type(s)

Principal Investigator

Contact name

Dr Peter O'Kane

ORCID ID

<http://orcid.org/0000-0001-5245-4547>

Contact details

Cardiac Department, Royal Bournemouth Hospital
Castle Lane East
Bournemouth
United Kingdom
BH77DW
+44 (0)1202303626
peter.o'kane@uhd.nhs.uk

Type(s)

Scientific

Contact name

Dr Jonathan Hinton

ORCID ID

<http://orcid.org/0000-0003-1670-5550>

Contact details

Cardiac Department, Royal Bournemouth Hospital
Castle Lane East
Bournemouth
United Kingdom

BH77DW
+44 (0)1202303626
jonathan.hinton@uhd.nhs.uk

Type(s)

Public

Contact name

Ms Sarah Savage

Contact details

Royal Bournemouth Hospital
Castle Lane East
Bournemouth
United Kingdom
BH77DW
+44 (0)1202303626
sarah.savage@uhd.nhs.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

British Orbital Atherectomy Registry (retrospective and prospective)

Acronym

BOAR

Study hypothesis

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Pending submission

Study design

Prospective observational study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital, Medical and other records

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Condition

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 measure

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

Secondary outcome measures

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

Overall study start date

01/01/2024

Overall study end date

01/01/2030

Eligibility

Participant 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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

300

Participant 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

Recruitment start date

01/06/2025

Recruitment end date

01/06/2028

Locations

Countries of recruitment

England

United Kingdom

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

Sponsor details

Castle Lane East

Bournemouth

England

United Kingdom

BH77DW

+44 (0)300 019 2025

researchsponsorship@uhd.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<https://www.uhd.nhs.uk>

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

Publication and dissemination plan

The dissemination strategy will be twofold. First, the results will be shared amongst medical professionals by presentation at international conferences and publication in a well-respected journal relating to interventional cardiology. Second, the results will be shared with the public in plain language across several platforms including the Trust research website and a dissemination event.

Intention to publish date

01/01/2030

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

