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Using light-based imaging to make heart stent treatment safer and more effective

Submission date 30/10/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 03/11/2025	**Overall study status** Ongoing	
Last Edited 16/12/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
When someone has a heart attack or other serious heart problem (called acute coronary syndrome or ACS), they tend to have worse outcomes than people treated for more stable heart conditions. Doctors usually use X-ray images (angiography) to guide treatment, but these images can sometimes be unclear. A newer technique called OCT (optical coherence tomography) gives much more detailed pictures from inside the blood vessels and may help doctors treat patients more effectively. This study aims to find out whether using OCT to guide treatment leads to better outcomes than using standard angiography in people with ACS.

Who can participate?
Adults aged 18 or older who come to hospital with a heart attack (either STEMI or NSTEMI) and whose symptoms started recently (within 12 hours for STEMI or 48 hours for NSTEMI) may be eligible. People who are very unwell (such as those in shock or with serious kidney problems) or unable to give consent cannot take part.

What does the study involve?
Participants will be randomly assigned to one of two groups. Both groups will receive standard care for their heart condition, including treatment of the blocked artery. One group will have their treatment guided by OCT imaging, while the other group will be treated using standard angiography. Doctors may also assess other arteries during the hospital stay. All participants will be followed up for one year to see how they are doing.

What are the possible benefits and risks of participating?
Taking part may help doctors better understand how to treat heart attacks more effectively. OCT imaging may offer more precise treatment, but it is not yet proven to be better. Risks are similar to those of standard heart procedures, including bleeding, allergic reactions, or complications from the procedure itself.

Where is the study run from?
Aarhus University Hospital in Denmark

When is the study starting and how long is it expected to run for?
September 2025 to November 2037.

Who is funding the study?
Abbott (Denmark)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2502300

Study information

Scientific Title
Optical coherence tomography in acute vessel evaluation

Acronym
OCTAVE

Study objectives
Routine OCT-guided PCI yields superior one-year clinical outcome compared with standard angiographic guided PCI.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 29/09/2025, The Medicinal Research Ethics Committees (MREC) Denmark (Ørestads Boulevard 5, Bygning 37K, st., København S, 2300, Denmark; +45 72 21 66 77; kontakt@dvmk.dk), ref: 2502300

Study design
Open label prospective randomized multi-center clinical outcome superiority trial

Primary study design
Interventional

Study type(s)
Diagnostic, Treatment

Health condition(s) or problem(s) studied

Optimizing percutaneous coronary intervention (PCI) for patients with ST-segment elevation myocardial infarction (STEMI) or non-ST-segment elevation myocardial infarction (NSTEMI)

Interventions

OCT guided group: OCT is a light-based intracoronary imaging technique that provides high-resolution cross-sectional images from inside the coronary arteries.
It enables detailed assessment of plaque characteristics, vessel and stent dimensions.
OCT is pre-defined to be performed before (pre-PCI) and after (post-PCI).
If the culprit lesion cannot be clearly identified on initial angiography, OCT will be used to determine the culprit lesion.
For non-culprit lesions, OCT is used to guides the decision for stenting according to predefined criteria (Distal external elastic lamina (EEL) reference diameter > 2.75 mm, and one of the following: 1) Significant thrombus or plaque rupture, 2) Minimum lumen area (MLA) < 2.0 mm^2 (or < 3.1 mm^2 in proximal LAD), 3) Lumen area stenosis > 75% or 4) MLA < 4.0 mm^2 with either thin-cap fibroatheroma (TCFA), thrombus, or lipid arc ≥ 90°).
Angiographic guided group: Control treatment follows current best clinical practice. OCT is not permitted. Intravascular ultrasound (IVUS) may only be used as a bailout option to resolve a critical procedural issue when no other diagnostic method is available or adequate. Centers using physiological measurements to guide treatment of non-culprit lesions may continue to do so according to local standard practice.
Follow-up: Follow-up is performed at 30 days, and at 1, 2, 3, and 5 years after the procedure. Each annual follow-up visit may occur within a ±6-week window around the target date and is conducted via telephone contact or outpatient visit.
Unscheduled follow-up is performed if a patient experiences or is suspected to have a SAE (serious adverse event). At 10 years, follow-up is done either registry-based or by phone call to assess death from any cause.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

OCT-guided PCI vs angiographic guided-PCI.

Primary outcome(s)

Combined endpoint of major adverse cardiac events (MACE). Comprising all-cause death, spontaneous myocardial infarction and stroke at 12 months

Key secondary outcome(s))

1. Major adverse cardiac events (MACE) are measured using clinical event adjudication of all-cause death, spontaneous myocardial infarction and stroke at 30 days, 36 months and 60 months
2. Patient-oriented composite endpoint (PoCE MACE) is measured using clinical event adjudication of all-cause death, any myocardial infarction, any unplanned revascularization and stroke at 30 days, 12 months, 36 months and 60 months
3. All-cause mortality is measured using clinical event adjudication and vital status records at 30 days, 12 months, 36 months, 60 months and 10 years
4. Cardiac death is measured using clinical event adjudication based on death certificates, hospital records and investigator reports at 30 days, 12 months, 36 months and 60 months

5. Spontaneous myocardial infarction is measured using the 4th Universal Definition of MI criteria applied to clinical records and biomarker data at 30 days, 12 months, 36 months and 60 months
6. Any ischemia-driven revascularization is measured using clinical event adjudication of coronary artery bypass grafting or PCI procedures excluding staged procedures at 30 days, 12 months, 36 months and 60 months
7. Any unplanned revascularization is measured using clinical event adjudication of repeat revascularization procedures not planned during the index procedure at 30 days, 12 months, 36 months and 60 months
8. Ischemia-driven target lesion revascularization is measured using clinical event adjudication of non-staged repeat PCI or CABG of lesions treated at index admission at 30 days, 12 months, 36 months and 60 months
9. Ischemia-driven target vessel revascularization is measured using clinical event adjudication of non-staged repeat PCI or CABG of vessels treated at index admission at 30 days, 12 months, 36 months and 60 months
10. Target lesion revascularization is measured using clinical event adjudication of non-staged repeat PCI or CABG of lesions treated at index admission at 30 days, 12 months, 36 months and 60 months
11. Target vessel revascularization is measured using clinical event adjudication of non-staged repeat PCI or CABG of vessels treated at index admission at 30 days, 12 months, 36 months and 60 months
12. Stroke is measured using clinical event adjudication based on neurological assessment and CT or MRI confirmation at 30 days, 12 months, 36 months and 60 months
13. Dyspnea severity is measured using the Rose Dyspnea Scale questionnaire at 30 days, 12 months, 36 months and 60 months
14. Angina severity is measured using the Canadian Cardiovascular Society (CCS) angina classification at 30 days, 12 months, 36 months and 60 months

Time-specific secondary endpoints:
15. Peri-procedural myocardial infarction is measured using ARC-2 and 4th Universal Definition criteria applied to biomarker and ECG data during or within 48 hours after the procedure
16. Stent thrombosis is measured using ARC-2 definitions of definite, probable or possible thrombosis at 30 days, 12 months, 36 months and 60 months
17. Contrast-induced nephropathy is measured using plasma creatinine levels with a >50% increase from baseline within 48 hours after the procedure

Procedural endpoints:
18. Contrast volume is measured using procedural records at baseline (index procedure and procedures staged within the same index admission)
19. Procedure time is measured using procedural records at baseline (index procedure and procedures staged within the same index admission)
20. Fluoroscopy time is measured using procedural records at baseline (index procedure and procedures staged within the same index admission)
21. Length of stents implanted in culprit lesion is measured using procedural records at baseline (index procedure and procedures staged within the same index admission)
22. Number of non-culprit lesions treated is measured using procedural records at baseline (index procedure and procedures staged within the same index admission)
23. Procedural failure is measured using procedural records indicating no stent implantation in target lesion at baseline (index procedure and procedures staged within the same index admission)

Angiographic endpoint:
24. Procedural success is measured using corelab quantitative coronary angiography (QCA) showing TIMI III flow and <30% diameter stenosis in target segments at baseline (index procedure and procedures staged within the same index admission)

Completion date
01/11/2037

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 16/12/2025:

Clinical:
1. NSTEMI, STEMI
2. Symptom duration < 12h for STEMI and <72h for NSTEMI
3. Age ≥ 18yrs
4. Ability to provide written informed consent

Angiographic:
1. Angiographic signs of at least one possible culprit lesion. Signs including acute occlusion, partial occlusion, proximal embolus, haziness, high grade stenosis, stent thrombosis
2. Wire in true distal lumen

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Previous key inclusion criteria:

Clinical:
1. NSTEMI, STEMI
2. Symptom duration < 12h for STEMI and <48h for NSTEMI -
3. Age ≥ 18yrs
4. Ability to provide written informed consent

Angiographic:
1. Angiographic signs of at least one possible culprit lesion. Signs including acute occlusion, partial occlusion, proximal embolus, haziness, high grade stenosis, stent thrombosis
2. Wire in true distal lumen

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
105 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Clinical:
1. Intravascular imaging evaluation of any lesions at index procedure
2. Cardiogenic shock
3. Sustained ventricular tachycardia or ventricular fibrillation
4. Planned CABG
5. Life expectancy < 1 year
6. Known severe heart failure with NYHA class ≥ III
7. Known ejection fraction < 30% before the admission
8. Known renal failure with GFR < 30 ml/min/1.73 m²
9. Active bleeding or coagulopathy
10. Relevant allergies (contrast media, aspirin, clopidogrel, ticagrelor, everolimus)
11. Suspected inability to lie flat for the duration of the PCI procedure
12. Inability to comply with the planned follow-up program
13. Known or anticipated compliance problems with medical therapy

Angiographic:
1. Study lesion involving the Left main coronary artery
2. Study lesion involving a true bifurcation lesion with a side branch > 2.5 mm
3. Severe tortuosity
4. Distal embolus
5. Isolated coronary artery spasm
6. Suspected spontaneous coronary artery dissection
7. Chronic total occlusions with treatment indication and no antegrade intra-plaque wire pass

Date of first enrolment
10/11/2025

Date of final enrolment
01/11/2027

Locations

Countries of recruitment
United Kingdom

England

Austria

Belgium

Denmark

Estonia

Finland

Germany

Ireland

Italy

Latvia

Netherlands

Norway

Poland

Sweden

Switzerland

Study participating centre
Bournmouth
Royal Bournemouth Hospital
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England
BH7 7DW

Sponsor information

Organisation
Aarhus University Hospital

ROR
https://ror.org/040r8fr65

Funder(s)

Funder type
Industry

Funder Name
Abbott Laboratories

Alternative Name(s)
Abbott, Abbott U.S., Abbott Alkaloidal Company

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
Limited and pseudo-anonymized data will be transferred to studies investigating the effect of OCT treatment across other studies, so-called meta-analyses. These meta-analyses will be carried out with Rigshospitalet (Copenhagen, Denmark) and the Cardiovascular Research Foundation (New York, USA). Full anonymization means that the information cannot be linked to individuals. The studies to which data are transferred comply with the General Data Protection Regulation and the Danish Data Protection Act. Data from this study will also be transferred to a project at Aarhus University investigating prognosis across patient groups treated with OCT.

IPD sharing plan summary
Available on request

Study outputs

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