

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

Submission date 30/10/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/11/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/11/2025	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

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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Contact information

Type(s)

Principal investigator

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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 guide 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 mm² (or < 3.1 mm² in proximal LAD), 3) Lumen area stenosis > 75% or 4) MLA < 4.0 mm² 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

Clinical:

1. NSTEMI, STEMI
2. Symptom duration < 12h for STEMI and <48h for NSTEMI -
3. Age \geq 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

Adult

Lower age limit

18 years

Sex

All

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 \geq 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
Leuven University Hospital
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3000

Study participating centre
Aalborg University Hospital
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Aarhus University Hospital Skejby
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København Ø
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2100

Study participating centre
Zealand University Hospital
Roskilde
Denmark
4000

Study participating centre
North-Estonia Medical Centre
Tallinn
Estonia
13419

Study participating centre
North Karelia Central Hospital
Joensuu
Finland
80210

Study participating centre
Vivantes Klinikum im Friedrichshain
Berlin
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10249

Study participating centre
Universitätsklinikum Schleswig-Holstein Campus Kiel
Kiel
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24105

Study participating centre
Gemelli General Hospital, Catholic University of the Sacred Heart
Rome
Italy
00168

Study participating centre
Latvia Centre of Cardiology
Riga
Latvia
1002

Study participating centre

Radboud University Medicine Center
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6525

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4604

Study participating centre
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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