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Optical coherence tomography to guide stent placement during percutaneous coronary intervention

Submission date 11/03/2015	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 11/03/2015	**Overall study status** Stopped	
Last Edited 04/06/2019	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Coronary artery disease (CAD) and its consequences are the leading cause of death and disease in the Western world, leading to major healthcare and economic burdens. CAD is the thickening of the walls of the coronary arteries that supply blood to the heart, caused by the build-up of fatty deposits in these blood vessels. Percutaneous coronary intervention (PCI) is a routine and widely used treatment to reopen narrowed or blocked coronary arteries. PCI is usually performed by feeding a hollow wire (catheter) through the blood vessels to the site of the blockage, inflating a balloon at the tip of the catheter to stretch the artery wall vessel and then placing an expandable metal tube (stent) at the site of the blockage. The stent stays in the wall of the artery in order to keep the artery wall stretched and allow blood to flow freely through the artery. Tools that can take pictures of the inside of the coronary arteries, have contributed substantially to our understanding of the how best to place a stent. Optical coherence technology (OCT) is a method for taking pictures of the inside of the coronary arteries, which provides an image with much greater resolution than current alternatives (e.g. intravascular ultrasound). The definition of the OCT images is at least ten times greater than with ultrasound, which enables very detailed imaging of the artery wall, the fatty deposits and, once placed, the stent. To date, there have been no studies of the usefulness of OCT for improving stent placement and the effectiveness of PCI. In this study we wish to assess whether routine use of OCT to guide stent placement will lead to improved stent placement.

Who can participate?
Patients aged 30 to 90 who are undergoing PCI for the treatment of CAD or acute coronary syndrome

What does the study involve?
Participants are randomly allocated to undergo either angiographically guided or OCT-guided stent placement. Angiographically guided stent placement is the standard care pathway, where a type of X-ray is used to examine the blood vessels. OCT-guided stent placement involves

taking pictures of the inside of the coronary arteries to guide decisions about the size and type of stent to use. All patients receive standard hospital follow up. 12 months after their procedure all patients complete a questionnaire.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
March 2014 to May 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18505

Study information

Scientific Title
Optical Coherence Tomography to guIde stent placeMent durIng percutaneouS coronary intErvention: a randomised controlled trial

Acronym
OCTIMISE

Study objectives
The aim of this study is to assess whether routine use of optical coherence technology (OCT) to guide stent placement will lead to improved stent placement and improved clinical outcomes at one year for people with coronary heart disease (CHD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands -Coventry and Warwick NRES committee, 25/02/2015, ref: 15/WM/0075E

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Cardiovascular disease; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
Following the consenting process the intervention begins in the Catheter laboratory:

1. Angiographically guided stent placement: This is the standard care pathway, the patient has their stent placed using standard treatment plan, once the clinician has stated that they have completed deployment the OCT catheter is taken past the stent(s,) this is known as a 'pullback', to visually record the inside of the lumen. The procedure ends. The patient has standard care and is discharged.
Duration is approximately 5 minutes longer than standard care.

2. OCT guided stent placement: After the standard angiogram and review of the lesions, the OCT catheter is used to visualise the inside of the lumen, the clinician uses the images to guide their decisions about size and type of stent used. The catheter is used again to check stent placement, the clinician makes any adjustments or corrections to the stent placement and if necessary another pullback is made to check the stent. Once the clinician is content, that the deployment is complete, a reference pullback occurs.

The procedure ends. The patient has standard care and is discharged. Duration is approximately 10 minutes longer than standard care. All patients receive standard hospital follow up. 12 months after their procedure all patients will receive a trial questionnaire.

Intervention Type
Procedure/Surgery

Primary outcome measure
To estimate the difference in minimal luminal area (MLA) immediately after the completion of PCI between the OCT-guided and the angiographically guided PCI groups. This outcome will be assessed by processing the digitally stored OCT images.

Secondary outcome measures
In the OCT-guided and angiographically guided groups:
1. To quantify and compare the prevalence of strut apposition, edge dissection and plaque prolapse. This will be determined from the images taken to assess the primary endpoint
2. To compare the nature and extent of additional interventions indicated from OCT images of the deployed stent, such as additional balloon dilations or further stenting
3. To quantify and compare the PCI procedure duration, the volume of contrast used and the X-ray dosage
4. To quantify and compare the number of major clinical events at 12 months follow-up

In OCT-guided group only:
Information about how the pre-deployment OCT images informed the choice of treatment strategy and stent

Overall study start date
04/03/2014

Completion date
01/05/2018

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
A participant may enter study if ALL of the following apply:
1. Adults of either sex aged 30 to 90 years who are undergoing EITHER,
1.1. Elective PCI for the treatment of CAD OR
1.2. Urgent PCI for the treatment of ACS

2. Patients who are willing and able to give written informed consent for participation in the study
3. Patients who are anticipated to have at least a 20 mm stent length in at least one lesion

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 128; UK Sample Size: 128

Key exclusion criteria
A participant may not enter study if ANY of the following apply:
1. Patients unable to provide written informed consent.
2. Patient undergoing emergency PCI
3. Patients that have had previous PCI within the target vessel.
4. Women who are pregnant or breast feeding
5. Haemodynamic instability
6. Renal impairment (eGFR =50 ml/min)
7. Multivessel PCI (>2 vessels) during a single procedure
8. Left main stem disease
9. Estimated angiographic vessel calibre <2.5mm or >4.5mm
10. Additional significant disease (>50% stenosis) in same vessel proximal or distal to culprit lesion
11. Target vessels / lesions of excessive tortuosity
12. Patients participating in another interventional study

Date of first enrolment
01/05/2015

Date of final enrolment
01/05/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Bristol Heart Institute
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust

Sponsor details
Research & Development
Upper Maudlin Street
Bristol
England
United Kingdom
BS2 8AE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The findings will be disseminated by usual academic channels, i.e. presentation at international meetings, as well as by peer-reviewed publications and through patient organisations and newsletters to patients, where available. We intend to publish as soon as possible.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No