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Comparing two methods of estimating the severity of individual narrowings in heart arteries, when there is more than one narrowing

Submission date
06/05/2021

Recruitment status
No longer recruiting

Registration date
14/05/2021

Overall study status
Completed

Last Edited
17/07/2025

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Angina and heart attacks are caused by narrowings within blood vessels supplying the heart. Individual narrowings that need treatment are usually identified by making an educated guess of the effect that each will have on blood flow, based on the appearance of the artery on an angiogram (an invasive x-ray procedure that involves injecting dye into each heart artery). However, doctors can now accurately determine the effect of a narrowing on blood flow using a pressure wire to measure fractional flow reserve (FFR) or instantaneous flow reserve (iFR) during the angiogram.
People who have blockages in the blood vessels in their heart are often offered a stent procedure. Research has shown that stent procedures are generally safe, prevent future heart problems and can improve people's symptoms. In a significant number of patients, the blood vessel supplying the heart (also known as coronary arteries) has more than one narrowing. In this situation it can be difficult to know which of the two or more narrowings require stenting. This study will investigate how accurate pressure wire measurement guided predictions are at determining the severity of each narrowing in a coronary artery.

Who can participate?
Patients are invited to join the trial if they are either scheduled to have a coronary angiogram which may show narrowings that require stenting, or have had an angiogram that demonstrated they have narrowings of the blood vessels in their heart and they need a stent procedure.

What does the study involve?
This study will involve 130 people having stent procedures. In order to make a fair comparison between the two commonly used pressure wire measurement methods (FFR and iFR), the researchers will perform both measurements in all patients. Patient management will be guided by one of these pressure wire methods, either FFR or iFR, this will be decided at random (like tossing a coin). The decision will not be made by the doctor.

What are the possible benefits and risks of participating?
There are no direct benefits from taking part in this study over the usual standard clinical care of

the patient's condition. The researchers will obtain very useful information from taking the extra measurements in the catheter laboratory using the pressure wires. The information from this study might help improve the treatment of patients with coronary artery disease in the future. Patients will not be paid for participating in the study.
As part of this study, the researchers will use an additional pressure wire (already used in clinical practice) to make additional recordings to normal care during which they will also be using a drug called adenosine. Therefore, if patients take part in this study, these additional recordings for research will result in their catheter laboratory procedure being lengthened by about 5 to 10 minutes with a small increase in time (no more than 1-2 minutes) exposed to the adenosine infusion but with no significant increase in the risk of the procedure. This increased procedural time will result in increased ionising radiation (X-ray) dose.

Where is the study run from?
Guy's and St Thomas' NHS Foundation Trust and Kings College London (UK)

When is the study starting and how long is it expected to run for?
September 2020 to August 2025

Who is funding the study?
Abbott Vascular (USA) with an unrestricted research grant to King’s College London (UK)

Who is the main contact?
Dr Matthew Li Kam Wa
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
293563

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 293563

Study information

Scientific Title
Systematic Evaluation by Randomisation of Intracoronary physiological techniques for Assessing tandem Lesions (SERIAL)

Acronym
SERIAL

Study objectives
To compare the accuracy of two different systems (that are routinely used clinically) for estimating the significance of individual lesions in serially diseased coronary arteries.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/08/2021, Wales Research Ethics Committee 1 (Health & Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0)1792 606334; Wales.REC1@wales.nhs.uk), ref: 21/WA/0238

Study design
Prospective multi-centre cluster randomized study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Coronary artery disease (CAD) with serial stenoses

Interventions
Randomisation will be stratified block randomisation with varying block sizes via the King's College London Clinical Trials Unit online portal. Blocks will be stratified by age and sex.

CAD with serial lesions will be assessed systematically in the same patient by the use of two intracoronary pressure sensing guide wires. In this way, both instantaneous wave free flow reserve (iFR) pullback Scout (Volcano Phillips) and fractional flow reserve (FFR) pullback solution (Abbott/Coroventis) can be compared. The operator will base medical strategy on the randomised modality only and be blinded to results from the non-randomised system.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
iFR Pullback (Volcano Phillips), FFR Pullback (Abbott/Coroventis)

Primary outcome measure
The accuracy of iFR Pullback (Volcano Phillips) and FFR Pullback (Abbott/Coroventis) at predicting the final Fractional Flow Reserve (ratio of distal and aortic pressures) after treatment of one lesion in serial coronary artery disease, measured using physiological intracoronary pressure measurements taken during an angioplasty procedure (baseline)

Secondary outcome measures
Secondary efficacy outcomes:
Change in management strategy following full physiological evaluation of serial coronary artery disease, assessed by operator questionnaire responses during the procedure (baseline)

Secondary exploratory outcomes:
Major adverse cardiovascular events (target vessel revascularisation, myocardial infarction, stroke, death), obtained through follow-up telephone calls at 30 days and 1 year

Overall study start date
24/09/2020

Completion date
01/08/2025

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 14/07/2021:
1. A focal lesion on angiography (at least 50% diameter stenosis) in a coronary artery
2. One of the following:
2.1. A second focal lesion (at least 50% diameter stenosis) which the operator would consider treating with separate (non-overlapping) stents
2.2. A segment of diffuse disease
3. Target vessel diameter of at least 2.5 mm, suitable for passing a pressure wire

Previous participant inclusion criteria:
1. A focal lesion on angiography (at least 50% diameter stenosis) in a coronary artery and either a second focal lesion (at least 50% diameter stenosis) or a segment of diffuse disease, which the operator would consider treating with separate (non-overlapping) stents
2. A vessel diameter of at least 2.5 mm, suitable for passing a pressure wire

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
130

Total final enrolment
87

Key exclusion criteria
1. ST-elevation myocardial infarction (STEMI)
2. Target vessel is considered the culprit for an Acute Coronary Syndrome (ACS) <72 hours before consent
3. Vessels protected by a graft with a history of previous coronary artery bypass grafting
4. Age <18 years
5. Unable to provide written informed consent (IC)
6. Known pregnancy or breastfeeding at time of randomisation

Date of first enrolment
23/08/2021

Date of final enrolment
01/08/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Royal Brompton Hospital
Sydney Street
London
United Kingdom
SW3 6NP

Study participating centre
Glenfield Hospital NHS Trust
Groby Road
Leicester
United Kingdom
LE3 9QP

Study participating centre
The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust
Royal Bournemouth General Hospital
Castle Lane East
Bournemouth
United Kingdom
BH7 7DW

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust

Sponsor details
Westminster Bridge Road
London
England
United Kingdom
SE1 7EH
+44 (0)2071887188
pals@gstt.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/Home.aspx

ROR
https://ror.org/00j161312

Organisation
King's College London

Sponsor details
The Strand
London
England
United Kingdom
WC2R 2LS
+44 (0)207 836 5454
kingshealthpartners@kcl.ac.uk

Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

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 researchers plan to publish the results of this study in leading peer-reviewed journals in the field of Cardiology. In addition, it is intended that the findings from this study will be presented as abstracts at key public meetings including the British Cardiovascular Society, European Society of Cardiology, American Heart Association, American College of Cardiology and Transcatheter Cardiovascular Therapeutics.

Intention to publish date
27/10/2024

Individual participant data (IPD) sharing plan
Anonymised intracoronary pressure data and basic demographic data will be stored on secure King's College London servers. Participants will be identified only by a unique study ID number. All patient identifiable data and procedure records will be held by individual recruiting hospitals in line with their own Information Governance policies. No identifiable data will be transferred to the central study team. All patients will have given informed consent on the use of their data, how and where it will be stored and for how long.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan		25/07/2024	25/07/2024	No	No
Results article		14/07/2025	17/07/2025	Yes	No