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The development of personalised approaches to improve the prevention of cardiovascular disease

Submission date 29/10/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 31/03/2021	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/08/2025	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Small blood cells called platelets help the blood to clot when we injure ourselves, but sometimes they form dangerous clots inside blood vessels that can cause heart attacks. People may be prescribed anti-platelet drugs that help to stop platelets from forming dangerous clots, but they do not work for everybody.
Researchers funded by the British Heart Foundation at the University of Reading have found that the way people's platelets work varies, and these differences might make certain anti-platelet drugs more or less effective for some people. These differences might be particularly important for people with Type II Diabetes, who are at increased risk of heart attacks and other forms of cardiovascular disease.
To understand if anti-platelet treatment can be safer and more effective, this study will recruit diabetic and non-diabetic patients with or without ischemic heart disease willing to donate small blood samples. These samples will be used to identify differences in the way platelets work in diabetic and non-diabetic patients and test the effectiveness of antiplatelet drugs in a lab.
This information will help researchers and clinicians understand why heart disease is more common in diabetic patients, assist in the development of new treatments and guide the use of existing antiplatelet drugs to maximise their safety and effectiveness for individual patients.
The aims are to increase understanding of the impact and mechanisms of platelet function that lead to worse outcomes associated with metabolic dysfunction which is common in this patient group.

Who can participate?
Patients undergoing coronary angiography (a procedure that uses X-ray imaging to see your heart's blood vessels)

What does the study involve?
During the patient's angiogram appointment, up to 50ml (Equivalent to 10tsp) of blood will be taken. We also collect body composition measurements such as height, weight, hip and waist circumference and body fat percentage. This will then be linked to measurements and results from tests using the patient's blood with information taken from their NHS hospital records

including the result of their angiogram.
As an optional part of the study, a small group of people will be requested to return for further blood sample analysis to ensure reproducibility. This is likely to be within 2 years of their angiogram appointment but may be up to 5 years after the start of the study.

What are the possible benefits and risks of participating?
No benefits but small additional risk in patients having blood taken

Where is the study run from?
The Royal Berkshire Hospital and the University of Reading (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?
1. British Heart Foundation (UK)
2. University of Reading (UK)
3. National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Jonathan Gibbins, j.m.gibbins@reading.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
285583

Protocol serial number
CPMS 46590, IRAS 285583

Study information

Scientific Title
Multi-parameter analysis of platelet function: the impact of cardiometabolic disease

Study objectives
This study expected to benefit patient care in a number of ways:
1. The establishment of personalised care pathways for specific patients, allowing patient stratification and therefore more effective therapy
2. Use of knowledge of how platelet function and regulation in obesity-related metabolic dysfunction to identify specific defects that may be targeted with new pharmacological strategies
3. The identification of new drug targets for these patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/09/2020, North West - Greater Manchester South Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8063; gmsouth.rec@hra.nhs.uk), ref: 20/NW/0364

Study design
Observational study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Ischaemic heart diseases, platelet function, diabetes mellitus

Interventions
A total of 400 patients will be recruited for this study (100 for each group):
1. Control Cohort without diabetes
2. Control Cohort with diabetes
3. Patients with IHD and without diabetes
4. Patients with IHD and diabetes

We require up to 50 ml blood sample taken from venous and/or arterial access during their clinic appointment at the hospital. We predict 10% of study participants to be recalled for further analysis a maximum of two times. Recalled patients will have the choice of blood sampling at either the Hospital or the University. We may also take body composition measurements.

A small group of volunteers available throughout the length of the study will also be recruited in order to ensure the equipment and quality of the testing remains high. They will be recruited by the University and there is no need to access medical information about the volunteers.

We will also be performing molecular analysis on the samples of recalled patients to identify molecular differences in platelet function between the groups.

A number of tested will be performed to understand which stage/ stages during platelet activation are affected in patients with ischaemic heart disease and diabetes. The tests performed will be carried out in an order which will make best use of the blood samples taken from each individual participant.

Intervention Type
Other

Primary outcome(s)
Platelet function measured by aggregometry and flow cytometry at baseline and optionally at a second time point likely to be within 2 years of the angiogram appointment but may be up to 5 years after the start of the study

Key secondary outcome(s))
Levels of thrombus formation measured using confocal microscopy at baseline and optionally at a second time point likely to be within 2 years of the angiogram appointment but may be up to 5 years after the start of the study

Completion date
31/08/2025

Eligibility

Key inclusion criteria
Under investigation for stable ischaemic heart disease and scheduled for coronary angiography as part of clinical care

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Acute Coronary Syndrome in the past 12 months
2. P2Y12 inhibitors (including clopidogrel, tricagreolor and prasugrel)
3. Treatment dose anti-coagulation, including warfarin or novel anti-coagulant drugs (NOACS)
4. Other metabolic dysfunction
5. Evidence of alcohol or drug misuse
6. Unable to give informed consent
7. Aged <18 years
8. Pregnancy
9. Active or recent malignancy (<2 years)
10. Any underlying haematological pathologies
11. Renal disease (eGFR <30)
12. Liver Cirrhosis

Date of first enrolment
04/01/2021

Date of final enrolment
28/02/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Reading
Institute of Cardiovascular and Metabolic Science
Harborne Building
Whiteknights Campus
Reading
United Kingdom
RG6 6AS

Study participating centre
Royal Berkshire Hospital
Royal Berkshire NHS Foundation Trust
London Road
Reading
United Kingdom
RG1 5AN

Sponsor information

Organisation
University of Reading

ROR
https://ror.org/05v62cm79

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation

Alternative Name(s)
The British Heart Foundation, the_bhf, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
National Institute for Health Research (NIHR) (UK)

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

Funder Name
University of Reading

Alternative Name(s)
The University of Reading, UoR

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

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
Participant information sheet	version V2.3		31/03/2021	No	Yes
Protocol file	version v2.1	14/12/2020	31/03/2021	No	No