

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

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| <b>Submission date</b><br>29/10/2020   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>31/03/2021 | <b>Overall study status</b><br>Ongoing            | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>18/08/2025       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> 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](mailto:j.m.gibbins@reading.ac.uk)

## Contact information

### Type(s)

Scientific

### Contact name

Dr Jonathan Gibbins

### ORCID ID

<https://orcid.org/0000-0002-0372-5352>

### Contact details

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## Additional identifiers

### EudraCT/CTIS number

Nil known

**IRAS number**

285583

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Screening

**Participant information sheet**

See study outputs table

**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 measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

01/09/2020

## **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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 400; UK Sample Size: 400

**Key exclusion criteria**

1. Acute Coronary Syndrome in the past 12 months
2. P2Y12 inhibitors (including clopidogrel, ticagrelor 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**

England

United Kingdom

**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

**Sponsor details**  
Whiteknights Campus  
Reading  
England  
United Kingdom  
RG6 6AS  
+44 (0)1183 787082  
m.j.proven@reading.ac.uk

**Sponsor type**  
University/education

**Website**  
<http://www.reading.ac.uk/>

**ROR**  
<https://ror.org/05v62cm79>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
British Heart Foundation

**Alternative Name(s)**

the\_bhf, The British Heart Foundation, 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)**

UoR

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United Kingdom

## Results and Publications

## Publication and dissemination plan

The outcomes from this study will be published in leading research journals such as Blood, Circulation, JACC and Nature Medicine, and will be presented at national and international research conferences such as the European Society of Cardiology, American Heart Association, and the International Society on Thrombosis and Haemostasis.

## Intention to publish date

01/08/2026

## 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? |
|---|--------------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> | version V2.3 |              | 31/03/2021 | No             | Yes             |
| <a href="#">Protocol file</a>                 | version v2.1 | 14/12/2020   | 31/03/2021 | No             | No              |
| <a href="#">HRA research summary</a>          |              |              | 28/06/2023 | No             | No              |