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Serial assessment of the index of microcirculatory resistance during primary percutaneous coronary intervention comparing manual aspiration catheter thrombectomy with balloon angioplasty (IMPACT study)

Submission date
24/03/2014

Recruitment status
No longer recruiting

Registration date
28/07/2014

Overall study status
Completed

Last Edited
01/07/2021

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Heart attacks are caused by a blood clot blocking the blood vessels of the heart, preventing blood getting to the heart muscle. Opening up the artery with a balloon (angioplasty) and a small mesh tube (stent) can cause this clot to break up and get washed downstream, which can make the heart attack worse. We have devices that can suck out the clot from the blood vessel (thrombectomy catheters). However, it is unclear whether patients benefit from this. We are interested in assessing blood flow and pressure in the blocked vessel to help guide the best use of these devices. We will assess the benefits of thrombectomy versus balloon angioplasty.

Who can participate?
Patients coming to the Cambridge Heart Attack Centre (Papworth Hospital) with a heart attack will be approached to participate in the study.

What does the study involve?
If you enrol in the study, there will be some additional stages to your angioplasty and stent procedure. The initial length of your hospital stay will not be altered by this study, but your procedure may take about 5-10 minutes longer. To assess the blood flow and pressure in your blocked artery causing your heart attack we will push a pressure/temperature wire past the blockage and take measurements using a drug called adenosine. These measurements will be performed three or four times (at each stage of your stenting procedure). We assess flow in the artery by injecting room temperature salt water into the artery, and measure temperature changes with a sensor on the wire tip. The pressure is also measured from tip of the wire. Adenosine will be given to you via a tube in your leg vein (inserted as part of your stenting procedure) each time we perform a pressure and flow assessment. Participants will be randomly allocated to receive treatment with either a clot suction device (thrombectomy microcatheter) and stents or will be managed with just balloon and stents alone (as is standard practice). After

your stenting procedure we will take extra blood tests at 6, 12 and 24 hours. We will also perform a cardiac MRI the day after your stent procedure whilst you are still an inpatient. Another MRI scan of the heart will be performed as an outpatient 3 months after your stent procedure. Finally we will contact you by telephone at 6 months and 1 year to find out how you are doing.

What are the possible risks and benefits of participating?
There is no direct benefit from being in the study. However, adenosine has been shown to reduce the size of heart attacks and may be cardio-protective. This is not currently given as part of standard care. All patients will be treated according to standard practice guidance. Your doctor will have detailed images of the heart from cardiac MRI that may help with your ongoing management. We believe that the risk to you is small because we will take care to only recruit suitable patients. The adenosine infusion can cause flushing, wheeze, shivers and mild chest tightness, but this resolves very quickly. The body rapidly breaks down adenosine and any side effects quickly resolve when the infusion is stopped. Participation in this study requires that you have 3-4 adenosine infusions, so that we can measure the pressure and blood flow at each stage of your stenting procedure. Injections of saline (salt water) into the coronary artery are made throughout the procedure to prevent the blood clotting in our equipment. You will not feel this and it is safe. In half of the participants a suction microcatheter will be used to retrieve clot from the artery (thrombectomy) before the stenting procedure. This will require about 1 extra minute of X-ray screening corresponding to a dose equivalent to 6 months of background radiation with an additional risk of radiation-induced cancer of 1 in 24,000. However, the routine angioplasty and stent procedure has a radiation dose of about 17 times this amount and the radiation exposure for the procedure is highly variable from individual to individual. There is no radiation involved in the cardiac MRI scans.

Where is the study run from?
Papworth Hospital NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
The study started in April 2012 and will run for 4 years.

Who is funding the study?
Biomedical Research Council (UK).

Who is the main contact?
Dr Stephen Hoole
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Contact information

Type(s)
Scientific

Contact name
Dr Stephen Hoole

Contact details
Papworth Hospital
Papworth Everard

Cambridge
United Kingdom
CB23 3RE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 2.0

Study information

Scientific Title
Serial assessment of the index of microcirculatory resistance during primary percutaneous coronary intervention comparing manual aspiration catheter thrombectomy with balloon angioplasty (IMPACT study): a randomized controlled pilot study

Acronym
IMPACT

Study objectives
Manual thrombectomy is superior to balloon angioplasty to maintain the microcirculation during primary percutaneous coronary intervention (PCI) treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 3 REC, 01/04/2012, ref: 08/H0306/49

Study design
Single-blind randomized controlled trial

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Acute myocardial infarction

Interventions
Participants will be randomised to receive one of the following two treatments:
1. Manual thrombectomy with a thrombus aspiration microcatheter (suction before stenting)
2. Balloon angioplasty with a balloon (stretch before stenting)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Index of Microcirculatory Resistance (IMR) at the end of the PPCI procedure

Secondary outcome measures
1. Troponin at 12 and 24 hours
2. Cardiac MRI determined infarct size at day 1 and month 3

Overall study start date
01/06/2010

Completion date
01/06/2014

Eligibility

Key inclusion criteria
1. Patients with ST segment elevation myocardial infarction (STEMI) or new left bundle branch block (LBBB), <12 hours since symptom onset and with partial restoration of coronary artery flow after passage of a guide wire
2. Age 18-100 years
3. Male or female

Participant type(s)
Patient

Age group
Other

Lower age limit
18 Years

Upper age limit

100 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Patient unable to consent
2. Cardiogenic shock
3. Unfavourable coronary anatomy
4. Surgical disease
5. Baseline Thrombolysis In Myocardial Infarction (TIMI) flow score = 0
6. Contra-indication to adenosine
7. Heart block
8. Severe airways disease

Date of first enrolment
01/06/2010

Date of final enrolment
01/06/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Papworth Hospital
Cambridge
United Kingdom
CB23 3RE

Sponsor information

Organisation
Papworth Hospital NHS Foundation Trust (UK)

Sponsor details
Papworth Everard
Cambridge

England
United Kingdom
CB23 3RE

Sponsor type
Hospital/treatment centre

Website
http://www.papworthhospital.nhs.uk/

ROR
https://ror.org/01qbebb31

Funder(s)

Funder type
Research council

Funder Name
Biomedical Research Council (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/05/2015		Yes	No