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PET CT analysis of restenosis after lower limb revascularisation

Submission date
12/06/2017

Recruitment status
No longer recruiting

Registration date
15/08/2017

Overall study status
Completed

Last Edited
08/04/2020

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims:
Peripheral arterial disease (PAD) is a common condition in which the blood flow to the legs is restricted. This happens because of the buildup of a fatty substance (plaque) on the walls of arteries. Over time this can cause the main arteries in the legs to become narrowed (stenosed) or blocked (occluded). As the arteries become narrower, patients begin the feel pain even when at rest and are at severe risk of developing ulcers or gangrene (acute lower limb ischaemia), which in severe cases can lead to amputation. For many patients, the only viable treatment option is to undergo surgery to restore blood flow. This is usually done using a procedure called an angioplasty (where a special balloon is inflated inside the affected artery to widen it) or an operation to bypass the blocked portion of the artery in the leg using a piece of another blood vessel. In some cases, arteries can become narrowed again after surgery (restenosis) however. A key challenge for blood vessel imaging is being able to predict restenosis in order to better understand the underlying biology and to allow tracking of the initial plaque's response to therapy. Work undertaken in Cambridge has shown that a type of imaging called positron emission tomography/computed tomography (PET/CT), which uses injectable radioactive dye, could be more accurate at tracking and monitoring plaques than standard techniques (involving ultrasound scans of blood vessels). The aim of this study is to look at examine the role of arterial inflammation and calcification both before and after a superficial femoral artery angioplasty.

Who can participate?
Men aged over 50 and women aged over 55 who are undergoing surgical treatment for PAD.

What does the study involve?
Participants who have an angioplasty scheduled are asked to attend the hospital twice prior to their surgery for scans. At each session, participants have their legs scanned with a PET/CT machine. They are given a small amount of tracer, inserted through a cannula (thing plastic tube) inserted into a vein. Participants also undergo a scan at the first session using an ultrasound (a scan that uses sound waves) to look at the blood flow of their legs. Participants then undergo their surgery. Six weeks after the surgery, the PET/CT scan is repeated. At 12 months after surgery, they undergo a final ultrasound scan.

What are the possible benefits and risks of participating?
There are no direct benefits with participating. There is a small risk of exposure to radiation due to the scans. There is a small and unlikely risks of allergic reaction or other side effects however the hospital has facilities to deal with this. Participant may experience discomfort when the cannula is placed into a vein, as well as bruising.

Where is the study run from?
Addenbrooke's Hospital (UK)

When is study starting and how long is it expected to run for?
November 2015 to October 2018

Who is funding the study?
British Heart Foundation (UK)

Who is the main contact?
Dr Mohammed Chowdhury

Contact information

Type(s)
Public

Contact name
Dr Mohammed Chowdhury

ORCID ID
http://orcid.org/0000-0003-0384-7197

Contact details
Box 212
Vascular Surgery
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Additional identifiers

EudraCT/CTIS number

IRAS number
167667

ClinicalTrials.gov number

Secondary identifying numbers
IRAS: 167667

Study information

Scientific Title
Multi-modality imaging to determine the role of calcification and inflammation on restenosis rates following lower limb angioplasty: The CIRLA Study

Acronym
CIRLA

Study objectives
Hypothesis:
Increased level of arterial wall inflammation and calcification predict restenosis risk following angioplasty of the superficial femoral artery.

Study aim:
The general aim of this project is to determine the role of arterial inflammation and calcification both pre- and post-intervention in risk of restenosis following superficial femoral artery angioplasty.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England - Cambridge East Research Ethics Committee, 10/09/2015, ref: 15/EE/0153

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Peripheral Arterial Disease

Interventions
Patients are identified from vascular clinic or vascular inpatient wards. As part of their usual clinical stream, participants are assessed and, if it is deemed appropriate, are scheduled to have a SFA angioplasty which is then booked.

Participants are then reviewed prior to this intervention and assessed for inclusion into the study (see inclusion/exclusion criteria). Eligible participants are approached and provided written information about the study. Participants are invited to the hospital on two separate days for a scanning session prior to the planned angioplasty. At each session the patient's legs will be scanned on a combined PET/CT machine. The scans will involve administration of a radioactive tracer. A cannula (thin plastic tube) will be inserted into the patient. The tracer will be injected through the cannula and the scans would be done 2 hours after the injection of the tracer. The technique is so sensitive that only a very tiny amount of the radioactive tracer is required. During the scan, patients are asked to lie flat on a bed on their back within the CT machine (which is shaped like a large doughnut). On the first of these days, patientsalso undergo an ultrasound scan of both legs to look at the blood flow through the arteries. Participants undergo their SFA angioplasty done to the standard level of care.

Six weeks after the angioplasty, participants return for their repeat PET-CT scans and are followed-up for 12 months thereafter. If participants undergo stenting at the time of angioplasty they are not invited back for the repeat PET-CT scan. At 12-months post angioplasty each participant have a final ultrasound duplex scan on completing the study.

Intervention Type
Device

Primary outcome measure
1. Primary patency, defined as SFA stenosis/anastamotic stenosis of < 50%, is measured using arterial duplex scanning at 12 months
2. FDG and NaF TBR measurements are measured using the scans at baseline and six weeks
3. Ankle-brachial pressure index bilaterally is measured using scanning at baseline
4. Blood markers and degree of disease are assessed using ultrasound duplex at baseline
5. Restenosis is measured using the ultrasound duplex at 12 months

Secondary outcome measures
Freedom from target lesion revascularization (TLR) at 1 year is measured by arterial duplex at 12 months.

Overall study start date
01/10/2015

Completion date
01/10/2018

Eligibility

Key inclusion criteria
1. Aged 50 years or over (women aged 55 years or over)
2. Symptomatic peripheral arterial disease (intermittent claudication / critical limb ischaemia)
3. Undergoing superficial femoral artery angioplasty (PTA) or femoro-popliteal vein bypass graft (FPBG)
4. Patients with TASC A and B lesions for the PTA group (there will be no restriction with regard to disease severity on the FPBG group as long as the anastomosis is to the popliteal artery)
5. Taking standard antiplatelet/statin medication

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Total final enrolment
50

Key exclusion criteria
1. Inability to undergo PET/CT
2. Presence of end stage renal failure
3. Metastatic malignancy
4. Patients undergoing adjunct endovascular procedures in the infrainguinal segments – PTA group only (e.g. Bare Metal Stent, Drug Eluting Balloon, Drug Eluting Stent)
5. Previous ipsilateral femoral artery angioplasty within the previous 6 months – PTA group only
6. Women under the age of 55 years
7. Patients with diabetes mellitus taking insulin

Date of first enrolment
01/11/2015

Date of final enrolment
01/07/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's Hospital
Cambridge University Hospital Trust
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
British Heart Foundation

Sponsor details
Lyndon Place
2096 Coventry Road
Sheldon
Birmingham
United Kingdom
B26 3YU
+44 300 330 3322
supporterservices@bhf.org.uk

Sponsor type
Research organisation

Website
https://www.bhf.org.uk

ROR
https://ror.org/02wdwnk04

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

Results and Publications

Publication and dissemination plan
Planned presentation at major cardiovascular meetings in the UK and USA, and publication in a major, high-impact, peer-reviewed cardiovascular journal.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mr Mohammed Chowdhury (mmc59@cam.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V3	26/08/2015	15/08/2017	No	Yes
Results article	results	01/04/2020	08/04/2020	Yes	No
HRA research summary			28/06/2023	No	No