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The VISION study: vascular inflammation imaging using somatostatin receptor positron emission tomography

Submission date 05/09/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/09/2014	**Overall study status** Completed	
Last Edited 02/08/2017	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims

In many people, as they get older, fatty deposits build up in the walls of the vessels which carry blood to the heart and brain. These fatty deposits are called plaques and occur as part of a process called atherosclerosis (hardening of the arteries). In some people, these plaques rupture and this can form a clot that blocks off the blood flow to the part of the body supplied by that vessel. This is how heart attacks and strokes occur. Atherosclerosis occurs over many years, and this causes gradual narrowing of vessels. Some people experience symptoms when the narrowing becomes severe, such as chest pain while walking. This is because the blood flow to the heart is limited. When people develop symptoms, we are able to perform tests such as x-ray angiography to detect these narrowed vessels. Once it is known that this process has occurred, medications can be given to help prevent heart attacks and strokes. However, many patients do not experience symptoms to warn them that they may be at risk of developing a heart attack or stroke. In fact, often the small plaques that do not cause symptoms are more prone to rupture. Therefore better ways are needed to identify people who are at increased risk of developing heart attacks and strokes before they occur, so that treatment can be started to help stabilise plaques and prevent future events. It is known from previous research that the plaques that are inflamed have a higher risk of causing problems. It is also known that if a plaque doesnt rupture, after a while the inflammation decreases and the plaques becomes hardened due to build-up of calcium and thickening of the tissue surrounding it. The tests that we currently use for look for signs of atherosclerosis in the neck and heart arteries, such as ultrasound and x-ray angiography, are not able to see inflammation in the vessel wall and therefore cannot predict whether a plaque is likely to cause a problem in the future. These tests can only tell us whether or not the inside of the vessels are already narrowed. Using a sophisticated type of scanning called Positron Emission Tomography (PET) it is possible to see areas of vessel wall inflammation by tagging inflammatory cells with radioactive substances called tracers that make them show up on images. PET imaging needs to be combined with a computed tomography (CT) scan so that we can see exactly where the areas of tracer are concentrated in the vessels. The CT scan can also show us if the vessels are calcified, and if we use contrast we can see if the inside of the vessels are narrowed. 18F-Fluorodeoxyglucose (FDG) is a PET tracer commonly used in cancer imaging, which we know can also show inflammation in the neck arteries. However, for several

reasons it is difficult to use 18F-FDG to look at inflammation in the heart arteries (which are smaller and constantly moving). The aim of this study is to see if inflammation in the fatty deposits in the neck and heart arteries can be detecting using PET imaging with a newer tracer, called 68Ga-DOTATATE, and to determine whether this tracer is better than FDG for this purpose.

Who can participate?
People who have had a recent heart attack or stroke, and also those who have evidence of narrowed arteries with some or no symptoms

What does the study involve?
The study involves attending the PET/CT department for two PET and CT scans focused on the heart and neck arteries. One PET scan is performed using 18F-FDG and the other with 68Ga-DOTATATE. As part of clinical care, some participants who have had a stroke go on to have an operation to remove a plaque from the blood vessels in the neck. This plaque is examined under a microscope to see how it compares with the results of the scans.

What are the possible benefits and risks of participating?
The PET scans use radioactive tracers, which are safe and are used in usual clinical practice without any serious side effects. There is also some exposure to radiation from the CT part of the scan. The results of this study will help to improve understanding of the causes of heart attack and stroke, and could help to improve the diagnosis and treatment of these conditions in the future.

Where is the study run from?
Cambridge University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
August 2014 to August 2016

Who is funding the study?
The Wellcome Trust (UK)

Who is the main contact?
Dr James Rudd
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02021188

Secondary identifying numbers
17323

Study information

Scientific Title
The VISION study: vascular inflammation imaging using somatostatin receptor positron emission tomography: a non-randomised trial

Acronym
VISION

Study objectives
This VISION study aims to investigate the role of inflammation in atherosclerosis using 68Ga-DOTATATE PET, and to validate 68Ga-DOTATATE PET imaging for the detection and quantification of vascular inflammation in the aorta, coronary and carotid arteries. This study will test the hypothesis that in subjects undergoing carotid endarterectomy for symptomatic plaques, there will be a positive correlation between carotid artery 68Ga-DOTATATE PET signal and the underlying degree of carotid inflammation measured by immunohistochemical analysis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East of England - Cambridge Central, 04/03/2014, ref: 14/EE/0014

Study design
Non-randomised; Interventional; Design type: Screening

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Topic: Cardiovascular disease; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
50 subjects with atherosclerosis will undergo sequential PET/CT imaging with 68Ga-DOTATATE and 18F-FDG, along with contrast angiography of the carotid and coronary arteries. Autoradiography and immunohistochemistry of excised carotid plaques will be used to validate the imaging data.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Correlation of 68Ga-DOTATATE PET signal to carotid plaque inflammation (time frame: baseline). This measure is correlation between carotid artery 68Ga-DOTATATE PET signal (TBR) and the underlying degree of carotid inflammation, measured by CD68 immunohistochemistry, in patients undergoing carotid endarterectomy.

Secondary outcome measures
Not provided at time of registration

Overall study start date
06/08/2014

Completion date
01/08/2016

Eligibility

Key inclusion criteria
Subjects with carotid artery disease:
Symptomatic subjects: 20
1. Age =40 years of age
2. Can provide written, fully informed consent
3. Have had a TIA or stroke within the preceding 4 weeks thought to be due to carotid artery atherosclerosis

Asymptomatic subjects: 10
1. Age =40 years of age
2. Can provide written, fully informed consent
3. Have at least a 30% stenosis in the carotid artery (control cohort)

Subjects with coronary artery disease:
Symptomatic and asymptomatic subjects: 20 total
1. Aged at least 40 years of age
2. Can provide written, fully informed consent
3. Have at least a 30% stenosis in =1 epicardial artery

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

Key exclusion criteria
1. Renal impairment (eGFR <30 ml/min)
2. History of contrast nephropathy
3. Atrial fibrillation
4. Any condition, in the opinion of the investigator, which prevents the participant from lying flat during scanning
5. Women of childbearing potential
6. Inability to provide written informed consent
7. Haemorrhagic stroke within 3 months of study entry
8. Total occlusion of a culprit carotid artery
9. Any medical condition, vital sign or laboratory value that, in the opinion of the investigator, makes the subject ineligible for inclusion

Date of first enrolment
06/08/2014

Date of final enrolment
01/08/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Division of Cardiovascular Medicine
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
Addenbrookes Hospital
Hills Road
Cambridge
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United Kingdom
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (UK); Grant Codes: 104492/Z/14/Z

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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	11/04/2017		Yes	No
HRA research summary			28/06/2023	No	No