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Florbetapir F18 (18F-AV-45) amyloid positron emission tomography (PET) imaging in focal dementia syndromes

Submission date
11/10/2011

Recruitment status
No longer recruiting

Registration date
08/11/2011

Overall study status
Completed

Last Edited
25/04/2018

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The purpose of this study is to gain a better understanding of the causes of different types of speech problems and other symptoms encountered in people with different forms of dementia. We hope that information obtained from this study will lead to further research which may enable earlier and more specific diagnosis of different forms of dementia.

Who can participate?
This study will involve 20 people with a diagnosis of dementia the majority of whom will have some form of speech or visual problem. Female patients must be aged over 55 years, male patients younger than 55 years can be admitted.
In addition about 5 people who are healthy and do not have symptoms of dementia will also be enrolled. These people can be male or female and aged 55 90 years.

What does the study involve?
If you agree to take part in the study, you will be asked to attend for a minimum of two and maximum of three days of testing. With your permission we will collect details of your general medical history and if you are a patient also review your medical records; we will interview you and someone accompanying you about your family history, physical and intellectual health, emotional well-being, speech, personality and behaviour. We will collect details about any current medications and perform a physical and neurological examination. Depending on whether you are already taking part in other research studies at the Dementia Research Centre, we may ask that you have some more detailed memory (psychometric) testing. You will not receive any details of the results of these tests. We will then arrange for you to have an MRI brain scan. An MRI is an electronic picture of brain structure created using a strong magnet instead of an X-ray. The scan should take about 40-50 minutes. You will lie on your back and enter the MRI machine. You will be asked to remain very still during the scan. During the study you will have two PET scans. PET stands for Positron Emission Tomography. A PET scan shows us how the brain uses many different chemicals. On one of the study days we will use PET to look at a particular protein (β amyloid) that occurs in Alzheimers disease. On a separate day we will look at the changes in glucose in the brain, which tells us how active the brain is. The scans use very

small amounts of radioactive substances called tracers to make the image. In this study we will use two tracers. One is called Florbetapir and shows up the protein (β amyloid) that occurs in Alzheimers disease; the other is called 18F FDG and shows how the brain uses glucose, which can be normal, increased or decreased. You must not be pregnant if you have a PET scan, and we will therefore not be involving women under the age of 55.

What are the possible benefits and risks of participating?
Participation in this study will not benefit you personally. However, we hope to gain new insights into the diagnosis and progress of dementia and hopefully this will contribute to helping others in the future. MRI: you may feel claustrophobic or uncomfortable lying in the MRI scanner. You will hear loud knocking noises but we will provide you with earplugs to wear during the MRI. You can ask to stop the MRI at any time if it becomes uncomfortable. PET/CT scanning: you may find the PET table to be uncomfortable to lie on during the scan and there is a small risk of discomfort, bruising, fainting, or infection with the tube in the vein used for checking your blood glucose and injecting the tracer. You can ask to stop the scan at any time if it becomes uncomfortable. There have been no known harmful reactions to the 18F FDG or Florbetapir compounds. Despite this, there is still the possibility of a rare allergic reaction. Both substances are radioactive and you will receive a small radiation dose from each, and from the scan itself. Adverse Events: to date, florbetapir F 18 has been tested in approximately 2,200 people in completed and ongoing studies. In the completed registration studies, the most common side effect the investigators considered to be associated with the drug was headache. There were other side effects, but none that occurred in more than one subject. Although the side effects from florbetapir F 18 noted so far have been relatively limited, there could be risks that we do not yet know about. If significant new risks become known during the study, we will inform you. There is currently no information on the effects of florbetapir F 18 on unborn children. However it is known that higher levels of radiation can cause damage to unborn children. If you are a woman who is still able to have children, or if you are pregnant or nursing, you will not be allowed to participate in this study. Venous cannulation (putting in an IV) is a routine medical procedure that has minimal risk when performed by trained personnel. Risks include blood clot, bruising and infection, but they are very small. Lightheadedness (dizziness) and fainting are also potential risks. To minimize these effects, the IV will be placed in the vein while you are lying down.

Where is the study run from?
The study is organised by researchers at the Dementia Research Centre (DRC) and Institute of Nuclear Medicine, University College London. The DRC is located in Queen Square in London (UK).

When is the study starting and how long will it run for?
The study is expected to start in November 2011 and run for one year.

Who is funding the study?
Funding for the research is from the UK Picks disease Support Group charity, and from a commercial company who manufactures the Florbetapir PET compound (Avid Radiopharmaceuticals).

Who is the main contact?
Dr Jonathan Schott
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Contact information

Type(s)
Scientific

Contact name
Dr Jonathan Schott

Contact details
University of London
Dementia Research Centre
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18F-AV-45-020

Study information

Scientific Title
Florbetapir F18 (18F-AV-45) amyloid PET imaging in focal dementia syndromes

Study objectives
1. To use florbetapir F18 to investigate the pathological underpinning of the neuropsychologically distinct variants of primary progressive aphasia (PPA) and to compare patterns of florbetapir F18 uptake between these patients and those with posterior cortical Alzheimers disease (PCA-AD) and age-matched controls.
2. To use 18F-fluoro-2-deoxy-D-glucose (FDG) PET imaging to assess the patterns of focal hypometabolism occurring in these disorders.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central London Research Ethics Committee, 03/10/2011, ref:11/LO/1124

Study design
Phase II single-centre diagnostic open-label non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Focal dementia syndromes - primary aphasia

Interventions
A single 300 MBq bolus injection of florbetapir F 18 will be administered to the patient 50 minutes prior to PET scan of the brain. Subjects are observed for 70 minutes after injection and a follow-up call within 3 days (+/- 1) monitors for late adverse events.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Florbetapir F 18

Primary outcome measure
Quantitative and qualitative assessments of florbetapir 18F uptake to test the primary hypotheses

Secondary outcome measures
Descriptive assessment of the focality and asymmetry of amyloid uptake and glucose hypometabolism between various groups

Overall study start date
17/11/2011

Completion date
17/11/2012

Eligibility

Key inclusion criteria
PPA Group
1. Are currently enrolled in the longitudinal study of frontotemporal lobular degeneration at the Dementia Research Centre (DRC) at University College London (UCL)

2. Patients with PPA will have undergone detailed neuropsychological assessments and will be classified in one of three syndromic groups: PNFA, LPA, or SD
3. Can tolerate a PET scan procedure

PCA-AD Group
1. 1. Are currently enrolled in the longitudinal study of posterior cortical atrophy at the Dementia Research Centre (DRC)
2. Patients with PCA-AD will have undergone detailed neurological assessments and will fulfil the following criteria:
2.1. Insidious onset of cognitive decline, sufficient to interfere with activities of daily living, with absence of structural lesion or significant whilte matter disease on magnetic resonnace imaging (MRI)
2.2. Relatively preserved episodic memory; deficits on standard psychological testing in at least two of four posterior cortical functions:
2.2.1. Object perception
2.2.2. Space perception
2.2.3. Calculation
2.2.4. Spelling
3. Can tolerate a PET scan procedure

Cognitively normal group
1. Have no cognition complaints
2. Are between 55 and 90 years of age
3. Give informed consent
4. Can tolerate a PET scan procedure

Participants may be male or female.
Subjects in the cognitively normal group must be aged 55 - 90 years.
Female subjects in the PPA and PCA-AD groups must be over 55 years and not have child bearing potential; male subjects may be younger.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
25

Key exclusion criteria
1. Have clinically significant hepatic, renal, pulmonary, metabolic, or endocrine disturbances
2. Have a clinically significant cardiovascular disease
3. Have a clinically significant infectious disease
4. Have a history of alcohol or substance abuse or dependence
5. Have a history of severe drug allergy or hypersensitivity
6. Women of child bearing potential

Date of first enrolment
17/11/2011

Date of final enrolment
17/11/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of London
London
United Kingdom
WC1N 3BG

Sponsor information

Organisation
Avid Radiopharmaceuticals Inc. (USA)

Sponsor details
3711 Market Street
Suite 710
Philadelphia
United States of America
PA19104

Sponsor type
Industry

Website
http://www.avidrp.com/

ROR
https://ror.org/01qat3289

Funder(s)

Funder type

Industry

Funder Name
Avid Radiopharmaceuticals Inc. (USA)

Funder Name
Picks Disease Support Group (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?
HRA research summary			28/06/2023	No	No