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Amyloid positron emission tomography (PET) imaging in the timely diagnosis of Alzheimer's disease

Submission date
20/05/2015

Recruitment status
No longer recruiting

Registration date
20/05/2015

Overall study status
Completed

Last Edited
23/04/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Alzheimer's disease (AD) is the most common type of dementia. It is most often characterised in its early stages by cognitive impairment, such as difficulty learning new things or trouble remembering. As it progresses, the symptoms of AD worsen due to the gradual death of brain cells. There are various factors considered to increase people's risk of developing AD, particularly family history of AD and increasing age, however the exact cause of AD is unknown. Increasing evidence supports a role of abnormally accumulated amyloid protein in the brain, which is thought to contribute to the development of AD. The results of recent studies measuring amyloid protein in the brains of people with memory problems suspicious of AD has shown that about 25% of patients may incorrectly be diagnosed with AD. These patients either had normal amyloid protein levels in the fluid found in the brain and spine (cerebrospinal fluid (CSF)), or no amyloid protein was detected on positron emission tomography (PET) brain scans. Misdiagnosis can have a significant effect on patients and may stop further medical investigations to determine the real cause of memory impairment, missing a potentially treatable cause. Conditions such as depression (with or without alcoholism), and vitamin B12 /folate deficiency are also associated with cognitive impairment and are not uncommon among older people. Early differentiation between AD and these conditions will inform practice and lead to correct and timely treatment for patients. The aim of this study is to assess the role of amyloid protein imaging using PET scans in confirming or excluding AD in patients with cognitive impairment.

Who can participate?
Adults aged 40 and over referred for memory problems.

What does the study involve?
All participants are given PET imaging scans to detect amyloid protein levels in the brain.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Sussex Partnership NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
May 2015 to February 2017

Who is funding the study?
1. Avid Radiopharmaceuticals, Inc. (USA)
2. Brighton and Sussex Medical School (UK)

Who is the main contact?
Dr N Tabet

Contact information

Type(s)
Scientific

Contact name
Dr Naji Tabet

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18884

Study information

Scientific Title
Role of amyloid positron emission tomography (PET) imaging in the timely diagnosis of Alzheimer’s disease in patients with underlying depression or vitamin B12/Folate deficiency: feasibility study

Study objectives

Early differentiation between Alzheimer's disease (AD) and depression (with or without alcoholism) or vitamin B12/folate deficiency using amyloid PET imaging will inform practice and lead to correct and timely management of patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Multicentre Research Ethics Committee (MREC), 06/02/2015, ref: 14/LO/2276.

Study design
Non-randomised interventional diagnosis/screening 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
Alzheimer's disease

Interventions
Amyloid PET imaging to visualise in vivo presence of amyloid deposits in the brain.

Intervention Type
Procedure/Surgery

Primary outcome measure
The primary outcome measure is to answer the question on whether the targeted use of the newly licensed amyloid PET imaging improves the diagnostic accuracy in patients presenting with cognitive impairment in addition to depression and/or vitamin B12 deficiency. This will be measured by calculating the number of patients whose diagnosis has changed post scan based on clinical decision.

Secondary outcome measures
1. Clinician confidence levels in the diagnosis measured pre and post scan using personally administered Likert scales
2. Distribution of amyloid in amyloid positive patients measured by amyloid PET imaging

Overall study start date
18/05/2015

Completion date
01/02/2017

Eligibility

Key inclusion criteria
1. Patients aged >40 referred to memory clinic
2. Presence of memory complaint suspicious of AD
3. Below normal scores on cognitive testing (CAMCOG, ACE III or sMMSE scores below the normal range)
4. Presence of specific co-morbid illnesses known to affect cognition and to complicate the diagnosis of Alzheimer's disease, namely depression and vitamin B12 deficiency
5. MRI and/or CT brain scanning done previously as part of routine diagnostic process

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
UK Sample Size: 10

Key exclusion criteria
1. Evidence obtained from history, physical examination or investigations which clearly support the diagnosis of conditions such as vascular dementia, dementia with Lewy bodies and frontotemporal dementia
2. Lack of ability to give informed consent
3. Inability to undertake PET scanning or previous allergic reaction to injected investigative nuclear medicine tracers
4. Positive pregnancy test in premenopausal women and breastfeeding
5. Inability to undertake PET scanning

Date of first enrolment
18/05/2015

Date of final enrolment
01/02/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sussex Partnership NHS Foundation Trust
Cognitive Treatment and Research Unit
Grove House
Southview Road
Southview Road
United Kingdom
TN6 1HB

Sponsor information

Organisation
Sussex Partnership NHS Foundation Trust

Sponsor details
Mill View Hospital
Sussex Education Centre
Nevill Avenue
Hove
England
United Kingdom
BN3 7HY

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05fmrjg27

Funder(s)

Funder type
Other

Funder Name
Avid Radiopharmaceuticals, Inc. (USA)

Funder Name

Brighton and Sussex Medical School (UK)

Results and Publications

Publication and dissemination plan

The results of this study will be presented at regional and national conferences. The results will also be published after data analysis in peer review journals.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		01/07/2016	23/04/2021	No	No
Poster results		01/07/2016	23/04/2021	No	No
HRA research summary			28/06/2023	No	No