

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

Submission date 20/05/2015	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 20/05/2015	Overall study status Completed	☐ Protocol
Last Edited 23/04/2021	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ 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 Najji Tabet

Contact details
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Additional identifiers

Protocol serial number
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.

Primary study design

Interventional

Study design

Non-randomised interventional diagnosis/screening study

Study type(s)

Diagnostic

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

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

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

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
HRA research summary			28/06/2023	No	No
Poster results		01/07/2016	23/04/2021	No	No