

A Study of the clinical Utility, patient preference and cost benefit of Spect and PET-CT brain imaging in the Evaluation and Diagnosis of Alzheimer's Disease

Submission date 12/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/05/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/09/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

7622

Study information

Scientific Title

A multicentre cohort study of the clinical utility, patient preference and cost benefit of single photon emission computed tomography (SPECT) and positron emission tomography computed tomography (PET-CT) brain imaging in the evaluation and diagnosis of Alzheimer's disease

Acronym

Suspected-AD

Study objectives

This study investigates which of two brain imaging techniques, single photon emission computed tomography (SPECT) or positron emission tomography combined with computed tomography (PET/CT) brain imaging, is more accurate in the diagnosis of different types of dementia (specifically Alzheimer's disease and dementia with Lewy bodies). We will recruit 100 subjects of both sexes who are aged over 60 years (40 with Alzheimer's disease, 30 with dementia with Lewy bodies, and 30 similarly aged controls) who will then undergo blood flow SPECT and glucose (FDG) PET/CT scanning.

The diagnostic accuracy of each scanning method compared to expert clinical diagnosis using validated criteria will be assessed. Scans will be assessed in a way similar to that used clinically, meaning that findings will be directly applicable to the wider NHS setting. We will also use questionnaires and willingness to pay methods to determine whether one scan is preferred over another by patients and carers. This study will be important in determining which form of brain imaging is best to use for assessing people with dementia, an important question since PET is much more expensive than SPECT and may prove slightly less acceptable to patients. The study will be conducted over a 3-year period (2 years for patient recruitment, one year for scan and data analysis).

More details can be found here: <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=7622>

Ethics approval required

Old ethics approval format

Ethics approval(s)

Newcastle & North Tyneside 1 Research Ethics Committee, 29/01/2010, ref: 09/H0906/88

Study design

Multicentre non-randomised diagnosis cohort study

Primary study design

Observational

Secondary study design

Cohort 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

Topic: Dementias and Neurodegenerative Diseases Research Network; Subtopic: Dementia;
Disease: Dementia

Interventions

Clinical assessment:

Motor features of parkinsonism will be assessed using the motor subsection of the Unified Parkinson's Disease Rating Scale (UPDRS III).

Cognitive assessment:

This will involve Cognitive testing with the Cambridge Cognitive Examination (CAMCOG), the Rey Auditory Verbal Learning Test) and executive function tests (verbal fluency and trails A & B). Standardised assessments of mood (Cornell scale for depression in dementia), neuropsychiatric features (Neuropsychiatric Inventory) and fluctuating attention will also be performed.

Imaging:

All participants will have a SPECT scan and a PET scan. Scans will be undertaken in a balanced order, so half of subjects will have the SPECT scan first followed by the PET, and half vice versa.

Preference questionnaires:

After each scan, patient and carer preference questionnaires will be administered. The carer would also be approached for a brief telephone interview 2 - 5 days after the scan.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Visual Reporting of scans (PET and SPECT), measured at baseline

Secondary outcome measures

1. Patient preference and cost, measured at end of recruitment phase
2. PET and SPECT maps compared for patients, measured at end of recruitment phase
3. Semi-automated region of interest analysis, measured at end of recruitment phase
4. Visual ratings of medial temporal lobe atrophy using the Scheltens scale, measured at end of recruitment phase
5. Visual ratings of scans on a semi-quantitative 4-point scale, measured at end of recruitment

phase

6. Voxel based analysis using SPM5, measured at end of recruitment phase

Overall study start date

01/04/2010

Completion date

31/12/2012

Eligibility

Key inclusion criteria

1. Diagnosis of probable Alzheimer's disease or probable dementia with Lewy bodies or healthy age matched controls
2. Aged over 60 years, either sex
3. Dementia patients to have mild to moderate dementia severity (mini mental state examination [MMSE] greater than 12)
4. Sufficient English to complete cognitive and psychiatric ratings

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

Planned sample size: 100; UK sample size: 100

Key exclusion criteria

1. Physical disability that would render the patient unable to undergo PET and SPECT scanning
2. Contraindications to PET or SPECT scanning
3. Unwillingness to undergo scanning

Date of first enrolment

01/04/2010

Date of final enrolment

31/12/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Newcastle University
Newcastle upon Tyne
United Kingdom
NE4 5PL

Sponsor information

Organisation

Northumberland, Tyne and Wear NHS Trust (UK)

Sponsor details

St Nicholas Hospital
Jubilee Road
Gosforth
Newcastle Upon Tyne
England
United Kingdom
NE3 3XT

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Ali.Zaatar@ntw.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.ntw.nhs.uk>

ROR

<https://ror.org/01ajv0n48>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme

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	07/09/2015		Yes	No