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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

Registration date
12/05/2010

Overall study status
Completed

Last Edited
21/09/2017

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Diagnostic

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Senior

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Northumberland, Tyne and Wear NHS Trust (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

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