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Differentiating Alzheimer's disease, amnestic mild cognitive impairment and normal aging

Submission date
18/03/2019

Recruitment status
No longer recruiting

Registration date
08/04/2019

Overall study status
Completed

Last Edited
02/03/2022

Condition category
Nervous System Diseases

[ ] 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 cause of senile dementia. The understanding and study of amnestic mild cognitive impairment (aMCI) (problems with memory) is important in the diagnosis of AD. Annually, about 15% of aMCI patients develop AD, and over a period of 7 years, 80% will develop AD. Modern neuroimaging techniques can aid the diagnosis of AD, particularly for aMCI patients. The aim of this study is to test the sensitivity of diffusion kurtosis imaging (DKI) for assessing differences in the brains of patients with Alzheimer's disease and aMCI.

Who can participate?
AD patients, aMCI patients, and healthy volunteers

What does the study involve?
DKI is used to inspect the hippocampus (part of the brain) of the three groups.

What are the possible benefits and risks of participating?
As the sensitivity of the DKI technique for the assessment of hippocampal differences between aMCI and AD patients has not been comprehensively investigated, this study served as an exploratory study of AD and aMCI.

Where is the study run from?
Shanghai Jiao Tong University Affiliated Sixth People's Hospital (China)

When is the study starting and how long is it expected to run for?
January 2010 to December 2018

Who is funding the study?
Shanghai Jiao Tong University School of Medicine (China)

Who is the main contact?
Dr Guoping Song
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1.0

Study information

Scientific Title
Differentiating Alzheimer’s disease, amnestic mild cognitive impairment and normal aging using diffusion kurtosis imaging parameters

Study objectives
To study the sensitivity of diffusion kurtosis imaging in assessing hippocampal differences between patients with Alzheimer’s disease and amnestic mild cognitive impairment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/05/2010, Ethics Review Board of Shanghai Jiao Tong University Affiliated Sixth People’s Hospital (Sun Xiuxiu, Ethical Office, 1st Floor, Teaching Building, 600 Yishan Road, Shanghai, China; Tel: +86 (0)2124056248), approval No. 2010(C)-6

Study design
Cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Alzheimer’s disease, amnestic mild cognitive impairment, normal aging

Interventions
This study comprised 20 Alzheimer’s disease patients (11 males and 9 females, mean, 73.2 ± 4.49 years), 20 amnestic mild cognitive impairment patients (10 males and 10 females, mean 71.55 ± 4.77 years), and 20 normal controls (11 males and 9 females, mean 70.45 ± 5.04 years). A 3.0T magnetic resonance scanner was utilized for diffusion kurtosis imaging to compare the difference in the hippocampus among the three groups.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Mean kurtosis measured by a 3.0T magnetic resonance scanner (MAGETOM, Verio, Siemens Healthcare, Erlangen, Germany), with a 32-channel head coil after hospitalization

Secondary outcome measures
Mean diffusion, fractional anisotropy and volume of bilateral hippocampus, measured by a 3.0T magnetic resonance scanner (MAGETOM, Verio, Siemens Healthcare, Erlangen, Germany), with a 32-channel head coil after hospitalization

Overall study start date
01/01/2010

Completion date
31/12/2018

Eligibility

Key inclusion criteria
The AD group was diagnosed according to the following criteria (McKhann et al., 1984):
1. Based on the Diagnostic and Statistical Manual of Mental Disorders IV and the National

Institute of Neurological and Communicative Disorders and Stroke/Alzheimer's Disease and Related Disorders Association criteria
2. A mini-mental state examination score of ≤ 23

Petersen diagnostic criteria were used to determine cases of aMCI (Petersen, 2004), according to:
1. Complaints of memory impairment confirmed by others
2. Objective evidence of memory impairment, e.g., memory test (delayed story recall test) scores lower than (age- and duration-) matched healthy controls by 1.5 standard deviations
3. An overall normal level of cognitive function, i.e., impairment is less than dementia level, Clinical Dementia Rating scale point = 0.5
4. Normal daily living skills, according to the Activities of Daily Living scale, mini-mental state examination score of < 26 points

In the normal control (NC) group, criteria are based on capacity for independence, normal findings on neurological examination and mini-mental state examination score of ≥ 28 points.

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Patients with history of hypertension, diabetes, mental illness, cancer, autoimmune or other diseases, or alcohol or drug abuse
2. Hachinski Ischemic Scale scores more than 4

Date of first enrolment
01/06/2010

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
China

Study participating centre
Shanghai Jiao Tong University Affiliated Sixth People's Hospital
No.600, Yishan Road
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Sponsor information

Organisation
Shanghai Jiao Tong University Affiliated Sixth People's Hospital

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/049zrh188

Funder(s)

Funder type
Government

Funder Name
Shanghai Municipal Education Commission - Gaofeng Clinical Medicine in China, No. 2016427

Funder Name
Clinical Science and Technology Innovation Project of Shanghai Shen Kang Hospital Development Center in China, No. SHDC22015038

Funder Name
Shanghai Municipal Science and Technology Commission Medical Guide Project in China, No. 16411968900

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Guoping Song (songgp1979@163.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2019	02/03/2022	Yes	No