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Assessing gray matter volume in patients with idiopathic rapid eye movement sleep behavior disorder

Submission date
11/10/2018

Recruitment status
No longer recruiting

Registration date
24/10/2018

Overall study status
Completed

Last Edited
31/01/2019

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
Idiopathic rapid eye movement (REM) sleep behavior disorder (iRBD) is a parasomnia, which is unusual nervous system activity during sleep. iRBD presents as limb movements, which often appear to act out the content of undesirable dreams. Patients and relatives complain about iRBD symptoms such as shouting, gesturing, leaping out of bed, or punching bed partners. iRBD is receiving increased attention as an important risk factor for the future development of neurodegenerative disorders, such as Parkinson's disease (PD). The cause remains unclear in iRBD patients. iRBD development is likely to stem from abnormalities in the structure of the brain. The development of imaging technology provides a new way to study such diseases, including functional and structural imaging. Functional imaging studies have reported that iRBD patients have regional cerebral perfusion and glucose metabolic changes. We aim to detect the changes in the structure of the brain, and find structural changes related to clinical indices in patients with iRBD. Our study's findings should provide more structural evidence for cerebral functional changes in this population.

Who can participate?
Adults who are diagnosed with iRBD at the Sleep and Wake Disorders Center in China

What does the study involve?
Patients will undertake the overnight polysomnographic (PSG) recordings. Only those patients who meet the clinical and PSG diagnosis criteria for iRBD can join this study. Patients will also receive a neurological examination and undertake various questionnaires. Besides, patients should receive the neurologic examination, Unified Parkinson's Disease Rating Scale motor rating (UPDRS III) and Mini-Mental State Examination (MMSE) score. All participants will also undertake high-resolution, structural MRI scans.

What are the possible benefits and risks of participating?
This study can expand the spectrum of reported structural changes in iRBD patients, having implications for the future research about such disease. In this study, iRBD patients can obtain the latest information about the progression of their disease, with no radiation. Based on the

clinical and imaging data, patients may regulate therapeutic plans to produce a better curative effect. There will be no immediate direct risk to those taking part. The main discomfort of taking MRI is loud noise during the scans.

Where is the study run from?
Sleep and Wake Disorders Center of the Department of Neurology and Radiology Department of Huashan Hospital, Fudan University (China)

When is the study starting and how long is it expected to run for?
January 2014 to December 2015

Who is funding the study?
1. China-US Biomedical Collaborative Research Program (USA, China)
2. National Natural Science Foundation of China (China)
3. Shanghai Sailing Program (China)

Who is the main contact?
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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0

Study information

Scientific Title

Exploring cerebral structural alterations using MRI and determining their association with clinical parameters in Idiopathic rapid eye movement sleep behavior disorder (iRBD) patients

Study objectives
To investigate the gray matter volume (GMV) changes, and the relationships between GMV and clinical indices, in iRBD patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of Huashan Hospital, 04/01/2014, ref: KY2013-336

Study design
Observational cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Idiopathic rapid eye movement sleep behavior disorder

Interventions
All iRBD patients underwent one night (8 hours) of audio-video-PSG monitoring. All MRI measurements were obtained on a 3-tesla GE Discovery MR750 Scanner for ~30minutes. Brain structural T1-weighted MRI scans was acquired from all 39 participants. Gray matter volume (GMV) data were analyzed based on Statistical Parametric Mapping 8, using a voxel-based morphometry method and two-sample t-test and multiple regression analysis. No follow-up data were obtained due to the nature of study design.

Intervention Type
Other

Primary outcome measure
Gray matter volume, assessed by MRI scans for 30 minutes at the study visit

Secondary outcome measures

Polysomnography monitoring over one night for 8 hours to assess:
1. Total sleep duration
2. Sleep efficiency
3. Stage 1 non-rapid eye movement (NREM)
4. Stage 2 NREM
5. Rapid eye movement sleep time
6. Apnea-hypopnea index
7. Phasic electromyography (EMG) activity index
8. Tonic EMG activity
9. Spontaneous microarousal index
10. Periodic limb movements in sleep

Overall study start date
02/01/2014

Completion date
10/12/2015

Eligibility

Key inclusion criteria
1. Aged 18–65 years
2. Diagnosed with iRBD according to the clinical and polysomnographic (PSG) characteristics

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
39

Key exclusion criteria
1. Signs of parkinsonism
2. Treated with psychotropic medications
3. Evidence of psychiatric disorders or dementia
4. Any cognitive impairment
5. Drug-induced iRBD
6. Sleep apnea syndrome
7. Electroencephalograph (EEG) abnormalities suggestive of epilepsy, central nervous system comorbidities such as brain tumor, encephalitis, unstable hypertension, and diabetes

Date of first enrolment
06/03/2014

Date of final enrolment
08/04/2015

Locations

Countries of recruitment
China

Study participating centre
Huashan Hospital, Fudan University
No.12, Urumqi Middle Road, Jing'an District
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Sponsor information

Organisation
Huashan Hospital, Fudan University

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05201qm87

Funder(s)

Funder type
Research organisation

Funder Name
China-US Biomedical Collaborative Research Program, No. 81361120393

Funder Name
National Natural Science Foundation of China, No. 81401135, 81671239

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
Shanghai Sailing Program, No. 18YF1403100.

Results and Publications

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

Intention to publish date
10/12/2016

Individual participant data (IPD) sharing plan
Individual participant data that underlie the results reported in this article will be published in a peer-reviewed journal, after deidentification (text, tables, figures, and appendices). It will be available to researchers who provide a methodologically sound proposal to achieve aims in the approved proposal. Proposals should be directed to zuoct_cn2000@126.com. To gain access, data requestors will need to sign a data access agreement. The study protocol, statistical analysis plan and informed consent form will also be available from 3 months up to 5 years following article publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2019		Yes	No