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Brain activation during sentence processing in Parkinson's disease: an event related functional magnetic resonance imaging study

Submission date	Recruitment status	[ ] Prospectively registered
28/12/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/12/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/11/2008	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR782

Study information

Scientific Title

Study objectives
We hypothesise that basal ganglia (BG) are involved in sentence processing whenever a sentence structure deviates from the predicted structure and this in order to inhibit the irrelevant structure and to switch to a revision process.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Not specified

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Parkinson's disease

Interventions
No interventions. It is observational research with the use of functional magnetic resonance imaging (fMRI) (no use of invasive techniques).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
For the fMRI analysis data, a main effect of group is expected. The level of activation in the BG will be reduced in the PD patient group compared to the healthy control group. For the within subject factors we expect to find a main effect of grammaticality. In the healthy elderly subject

group, we expect that the processing of the grammatically incorrect sentences will activate the BG more compared to the processing of the grammatically correct sentences. For the behavioural data, we expect to find slower reaction times (RTs) for the processing of non-canonical ungrammatical sentences (i.e. passive sentences with a violation) in both subject groups. However the RTs will be significantly more affected in the PD group compared to the healthy elderly subject group.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/12/2006

Completion date
01/12/2007

Eligibility

Key inclusion criteria
1. Idiopathic Parkinson's disease (PD)
2. Hoehn and Yahr stage 1 to stage 3
3. Normal vision and hearing
4. Able to give informed consent
5. Older than 40 years
6. Dutch as first language
7. Right-handed
8. Normal structural magnetic resonance imaging (MRI) scan

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
32

Key exclusion criteria
1. Not optimally medicated
2. Neurostimulator
3. Implanted pump (e.g. apomorphine)
4. Dementia (Mini Mental State Examination [MMSE] score less than 25)
5. Depression (Montgomery-Asberg Depression Rating Scale [MADRS] more than 18)
6. Another neurological disease
7. Another akinetic-rigid disorder
8. Another movement disorder
9. No normal structural MRI scan

Date of first enrolment
01/12/2006

Date of final enrolment
01/12/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Oude Kijk int Jatstraat 26
Groningen
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9712 EK

Sponsor information

Organisation
University of Groningen (The Netherlands)

Sponsor details
Faculty of Arts
Neurolinguistics
Postbus 196
Groningen
Netherlands
9700 AD

Sponsor type
University/education

Website
http://www.rug.nl/corporate/index?lang=en

ROR
https://ror.org/012p63287

Funder(s)

Funder type
Industry

Funder Name
Stichting Internationaal Parkinson Fonds (The Netherlands)

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