Study to investigate mutations in the GBA1 and LRRK2 genes in Parkinson’s Disease patients.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23101

Source
NTR

Brief title
GBA1 and LRRK2 screening

Health condition

Parkinson’s Disease

Sponsors and support

Primary sponsor: CHDR
Source(s) of monetary or material Support: CHDR

Intervention

Outcome measures

Primary outcome

• Sequence of the GBA1 gene

• Presence of 7 specific mutations in the LRRK2 gene

Secondary outcome

Database of genotyped PD patients, for future research on PD

Study description

Background summary

For a upcoming Phase I B study (CHDR1 710), investigating a possible first-in-class disease modifying drug, 28 Parkinson's disease patients with a GBAI mutation (PD-GBA+) are needed. This is a mutation that occurs in approximately 5-10% of PD patients. There is no way to phenotypically differentiate between PD patients with and without a GBAI mutation. ln order to identify these patients, a large-scale screening is needed. Another gene which is known to be involved in the Parkinson's disease process is the LRRK2 gene. This gene is also a possible target for novel treatments, currently being investigated. ln order to perform proof-of-concept or efficacy studies of such treatments, a database of genotyped PD patients is important in order to be able to efficiently enroll a relevant subject population. The patients will be recruited in the Netherlands.

Study objective

Genotyping of the full GBAI gene in people with Parkinson's Disease, assessed as wildtype (GBA-) or containing a mutation (GBA+); the specific mutation will be recorded as well. Assessing the presence of 7 known PD-causing mutations in the LRRK2 gene in people with Parkinson's Disease, assessed as wildtype (LRRK2-) or containing a mutation (LRRK2+); the specific mutation will be recorded as well. Storage of DNA, obtained through saliva, for possible further assessments of genes related to Parkinson's Disease in the future.

Study design

• 1x (at home) saliva kit.

Intervention

NA

Contacts

Public

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Eligibility criteria

Inclusion criteria

• Signed informed consent prior to any study-mandated procedure

• Diagnosis of Parkinson’s Disease, diagnosed by a neurologist

• Has the ability to communicate well with the Investigator in the Dutch language and willing to comply with the study restrictions

Exclusion criteria

NA

Study design

Design

Study type:	Observational non invasive

Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-04-2017
Enrollment:	1000
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-05-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45734
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6252
NTR-old	NTR6426
CCMO	NL61137.056.17
OMON	NL-OMON45734

Study results