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

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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…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23101

Bron
Nationaal Trial Register

Verkorte titel
GBA1 and LRRK2 screening

Aandoening

Parkinson’s Disease

Ondersteuning

Primaire sponsor: CHDR
Overige ondersteuning: CHDR

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• Sequence of the GBA1 gene
• Presence of 7 specific mutations in the LRRK2 gene

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

• 1x (at home) saliva kit.

Onderzoeksproduct en/of interventie

NA

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

NA

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	03-04-2017
Aantal proefpersonen:	1000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-05-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45734
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6252
NTR-old	NTR6426

Register	ID
CCMO	NL61137.056.17
OMON	NL-OMON45734

Resultaten