Neuroinflammation in the pathogenesis and progression of Parkinson's disease

Published: 12-09-2006
Last updated: 20-05-2024

This study aims to show increased microglia activation in brain parts involved in PD pathology, comparing PD patients with age-matched healthy control subjects. To see whether microglia activation changes early in the course of Parkinson*s disease (...

Ethical review	Approved WMO
Status	Pending
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational invasive

Summary

ID

NL-OMON30138

Source
ToetsingOnline

Brief title
Neuroinflammation in Parkinson's disease

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Michael J Fox Foundation

Intervention

Keyword: Neuroinflammation, Parkinson's disease, PK-11195 PET

Outcome measures

Primary outcome

Uptake of the radiolabeled PK11195 measured with PET as a measure of activated

microglia in neuroinflammation. The groups will be statistically compared using

an SPM programme.

Secondary outcome

not applicable

Study description

Background summary

The cause of Parkinson's disease is unknown. Neuroinflammation is suggested to play a role in the progression of neurodegeneration. Neuroinflammation can be measured in vivo in patients with PET and radiolabeled PK11195. Finding the source pathogenic mechanisms triggering this neurodegenerative disease is needed to develop effective neuroprotective intervention.

Study objective

This study aims to show increased microglia activation in brain parts involved in PD pathology, comparing PD patients with age-matched healthy control subjects.
To see whether microglia activation changes early in the course of Parkinson*s disease (PD), de novo PD patients will be compared to patients in later stages of the disease.

Study design

Prior to entering the PET study, subjects will undergo general medical and neurological screening. If subjects fulfill the criteria for entering the study, in a next visit they will undergo a [11C]-PK11195 PET scan and MRI scan of the brain.
Images will be analysed and groups will be compared using a Statistical

Parametric Mapping (SPM) programme.

Study burden and risks

PET scan with radiolabeled PK11195 results in minimal radiation load. Bleeding risk after blood sampling with the scan will be minimised by applying pressure on site of sampling. Subjects are asked to be able to lay without moving their head in the PET scanner during one hour.

Contacts

Public
Academisch Medisch Centrum

Hanzeplein 1
9700 RB Groningen
Nederland
Scientific
Academisch Medisch Centrum

Hanzeplein 1
9700 RB Groningen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria (healthy volunteers)

Age over 40
Informed consent;Inclusion criteria (patients)
-Age over 40
-Informed consent.
-Regarded by the treating physician to have competence of judgement.
-Compliance with the criteria for possible or probable PD as proposed by Gelb, Oliver and Gilman [1999]
-de novo PD without PD medication, or advanced PD with Hoehn and Yahr stage of at least 2.

Exclusion criteria

Exclusion criteria (all PET-study subjects)
- Prior cardiovascular brain disease, other brain disease (including former traumatic contusion)
- Evidence of any general medical disease, e.g. significant kidney or liver disease, evidence of autoimmune disease.
- Use of anti-inflammatory medication: NSAID*s and steroids.
- Use of benzodiazepines. Benzodiazepines have affinity for the PBR receptor that binds the PET tracer PK11195 and can interfere with the study.
- Abnormalities at clinical neurological examination
- Pregnancy in women of childbearing potential.
- Exposure to a significant amount of radiation in the past year.
- Radiological workers.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2006

Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL13492.042.06