Parkinson-PEST: Preventing Emergence of Symptoms by environmental Toxicants identification

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The main objective of this study is to investigate the role of environmental factors in general, and pesticides in particular, in the aetiology of PD.

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

Summary

ID

NL-OMON57543

Source
ToetsingOnline

Brief title
PD-PEST

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van LNV en Radboud Fonds

Intervention

Keyword: Epidemiology, Parkinson's disease, Toxicants

Outcome measures

Primary outcome

The main study parameter is the difference in lifetime exposure to pesticides between cases and controls. Lifetime exposure will be estimated using complementary modalities that focus on occupational, residential, and household exposure. Exposure will be assessed using three complementary modalities: questionnaires, existing databases (medication records, the residential history from the *personal records database*, and pesticide use database), and measurements (blood, saliva, faeces, ultrasound measurements of bone, and via silicone wristbands). Furthermore, the study design allows assessment of other external factors that may be associated with the risk of PD. We will specifically quantify exposure to the following three groups of other external factors: heavy metals, solvents, and air pollution. If other potential risk factors of PD emerge during the study, we intend to also assess exposure to those factors by leveraging materials that have already been collected at baseline (if applicable) in order to answer future questions. Additionally, clinical progression of cases will be serially assessed for 36 months using an annual follow-up questionnaire. In the Nijmegen region, we will expand annual follow-up by using silicone wristbands and wrist-based sensors to assess exposure and clinical progression, respectively.

Secondary outcome

See above.

Study description

Background summary

Parkinson*s disease (PD) is the fastest growing neurological disease in the world. Recent evidence suggests that a part of the PD disease burden can be explained by exposure to environmental factors such as pesticides. However, insight on the extent of their role in the aetiology of PD remains scarce.

Study objective

The main objective of this study is to investigate the role of environmental factors in general, and pesticides in particular, in the aetiology of PD.

Study design

In this hospital-based case-control study, the exposure to pesticides and other environmental factors will be mapped in a representative sample of persons with newly diagnosed PD and age- and sex-matched controls in the Netherlands.

Study burden and risks

After informed consent, data collection for this study will consist of questionnaires (baseline and follow-up) and biological material. We will also access existing databases. Study participation includes one study visit at baseline, during which blood and saliva are collected and bone metal is measured (Nijmegen region only). All other assessments can be performed remotely, including self-collection of faeces. The estimated duration of the assessments are 100 minutes for the questionnaire at baseline for cases and 45 minutes for controls, 25 minutes for measurements during the study visit, 10 minutes for self-collection of faeces (cases only), and 55 minutes for the follow-up questionnaire (cases only). Wristbands are worn for two weeks and wrist-based sensors (only cases in Nijmegen region) for one week. Overall, we believe that burden and risks associated with participation are limited. Both cases and controls may withdraw from the study at any time.

Contacts

Public
Radboud Universitair Medisch Centrum

Reinier Postlaan 4
Nijmegen 6525GC

NL
Scientific
Radboud Universitair Medisch Centrum

Reinier Postlaan 4
Nijmegen 6525GC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Cases:
- Incident Parkinson*s disease;
o Defined as <=1 month since diagnosis was made by a neurologist in the Netherlands at the moment of recruitment.
- Aged >=18 years;
- Willing and able to provide informed written or digital consent.

Controls:
- Diagnosed with one of the following specific set of diseases:
o A median nerve neuropathy due to entrapment in the carpal tunnel (carpal tunnel syndrome), ulnar nerve neuropathy or compressive peroneal nerve neuropathy which is not related to a trauma or autoimmune disease;
* Confirmed by a clinical diagnosis combined with electromyography and/or ultrasound.
o Disc herniation (hernia);
o Sciatica;
o Lumbago;
o Radiculopathy.
- Aged >=18 years;

- Willing and able to provide informed written or digital consent.

Exclusion criteria

Cases:
- Initially diagnosed in a non-participating centre and referred to one of the participating hospitals for follow-up care or a second opinion.
- Other neurodegenerative diseases (e.g. atypical parkinsonism, ALS, or a dementia subtype which is not related to PD).

Controls:
- Diagnosed with Parkinson*s disease at the time of inclusion;
- Blood relative or spouse of a case selected by the same department of neurology to prevent over matching;
- Initially diagnosed elsewhere and referred to one of the participating hospitals for follow-up care or a second opinion;
- Other neurodegenerative diseases (e.g. atypical parkinsonism, ALS, dementia) at time of inclusion.

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	4500
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	22-05-2025
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL86526.091.24