REAL_PD: development of clinical prognostic models for Parkinson*s disease from large-scale wearable sensor deployment and clinical data - a population-based trial

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

Summary

ID

NL-OMON42375

Source
ToetsingOnline

Brief title
REAL_PD trial

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson□s disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Michael J. Fox Foundation for Parkinson's Research,Philips

Intervention

Keyword: Ambulatory sensors, Parkinson□s disease, Prognostic indicators

Outcome measures

Primary outcome

Study endpoints include parameters registered with the smartwatch, the pendant movement sensor, and collected with the PPMI assessment. The data from the smartwatch is processed into parameters for the amount of time active during the day and the number of steps per day. If the ongoing work in develop algorithms is successful, it may become possible to predict ON/Off levels, bradykinesia, dyskinesia and rigidity. The number of falls will be registered with the pendant movement sensor (necklace). Medication intake and mood are registered using an app on the Smartphone. Finally, the PPMI assessment includes assessment of motor symptoms, cognition, depression, sleep and daily activity.

Secondary outcome

not applicable

Study description

Background summary

Today*s management of patients with a chronic disorder like Parkinson*s disease (PD) is imperfect. Our understanding of clinical profiles is based on

observations in small, selective populations with brief follow-up. Moreover, treatment decisions are based on averaged population results that may not apply to a specific individual context. These drawbacks will be addressed with a *big data* approach. Ambulatory sensors will be used as an objective measure of patients* performance under everyday circumstances, for longer periods of time. We aim to explore the potential of using longitudinal ambulatory data to enrich a standardized clinical dataset, which reflects current clinical practice for the assessment of disease status.

Study objective

The study will include a total of 250 physiotherapists and 1000 patients. The aims of this study are: (1) to perform *big data* analyses on the raw sensor data, in relation to concurrently acquired clinical data in these patients (limited version of the PPMI protocol); and (2) to correlate the ambulatory sensor data to simple self-assessments made during follow-up.

Study design

Observational longitudinal cohort study.

Study burden and risks

Using the ambulatory devices data will be recorded 24/7, for a total duration of 13 weeks. Participants will wear the devices continuously, during 13 weeks. Second, data from watch and smartphone app will be transmitted to a data platform developed and managed by Intel, on behalf of the Michael J. Fox Foundation for Parkinson`s Research. Data from the movement monitor and the fall diary will be transmitted to Philips. Only coded data will be transmitted to the Intel*s and Philips platform.
To access those data, researchers can grant permission for research purposes, provided by these companies. Accordinly, patients will be asked for permission to share the raw data in a coded form for dissemination to the research community, analysis and use in future publications. Only data of those patients that provided written permission will be used accordingly. This approach does not give a breach of privacy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Dutch Parkinson patients
- Male or female
- Age 30 years or older at time of PD diagnosis
- Subjects must have at least two of the following: resting tremor, bradykinesia, rigidity (must have either resting
tremor or bradykinesia); OR either asymmetric resting tremor or asymmetric bradykinesia
- Ability to provide written informed consent in accordance with Good Clinical Practice (GCP), International
Conference on Harmonization (ICH), and local regulations

Exclusion criteria

Little or no response to adequate doses of levodopa or a dopamine agonist
- Atypical PD syndromes due to either drugs (e.g., metoclopramide, flunarizine, neuroleptics) or metabolic
disorders (e.g., Wilson*s disease), encephalitis, or degenerative diseases (e.g., progressive supranuclear palsy)
- A clinical diagnosis of dementia as determined by the investigator
- Any other medical or psychiatric condition or lab abnormality, which in the opinion of the

investigator might
preclude participation
- Previously obtained CT MRI scan is suggestive of another cause of parkinsonism, or with evidence of clinically
significant other neurological disorder (in the opinion of the investigator)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-08-2015
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO Date:	13-07-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-08-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-11-2015
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-12-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-04-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-07-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-11-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-03-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-06-2017
Application type:	Amendment
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	NL53034.091.15