Ambulatory monitoring of postural instability and gait disorder in Parkinson's Disease.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23798

Source
NTR

Brief title
AMPIGD_PD

Health condition

Ambulatory moniotring
Parkinson's Disease
Kinematics
PIGD

Sponsors and support

Primary sponsor: Dr. J.P.P. van Vugt
j.vanvugt@mst.nl
Medisch Spectrum Twente
Afdeling neurologie
Postbus 50000
7500 KA Enschede
+31 (0)53-487 2841

Dr. Ir. T. Heida
Function: Assistant professor

Biomedical Signals and Systems
University of Twente
Drienerlolaan 5
7522 NB Enschede
Building: Zuidhorst 226
+31 (0)53 489 2759

S. Sharifi
s.sharifi@student.utwente.nl
MSc. Student Technical Medicine
Medical Signalling
+31 (0)53 4873064
Source(s) of monetary or material Support: Dr. J.P.P. van Vugt
j.vanvugt@mst.nl
Medisch Spectrum Twente
Afdeling neurologie
Postbus 50000
7500 KA Enschede
+31 (0)53-487 2841

Intervention

Outcome measures

Primary outcome

The subjects walk in a defined environment with six sensors and all activities will be filmed in order to correlate postural disability and gait disorders with the signals registrated by the sensors. The characteristics in gait are to be detected that cause PIGD and the corresponding signal. From this data several features are extracted that would be able to detect and classify PIGD.

Furthermore, with the appointed features an optimal and minimal sensor configuration (amount and position of sensors) will be determined in which these features are still effective in detection and classification.

Secondary outcome

During the measurements also clinical tests are conducted (UPDRS 10 meter timed walking test + Timed-Up-and-Go), which give a clinical assessment of the stadium of the disease. The features that are derived from the sensors are correlated with the clinical scales.

Study description

Background summary

Subjects are required to perform a predefined walking trail along a total of 75 m leveled walkway at self-selected preferred speeds. The measurements are subdivided in three sections which will be monitored with 6 sensors including a walking trajectory where tasks are performed which can elicit their walking disabilities and short while free walking (3 min). Furthermore the standard physiotherapy examination performed for Parkinson screening are included in the measurement. At last the UPDRS scale (part III) is obtained. Two questionnaires are asked to be filled in, the Falls efficacy scale and freezing of gait questionnaire. These measurements will be performed in a defined gym with an even floor at the physiotherapy department of hospital. Patients will be tested during their subjective on/off phase, using their regular medication regimen. The subjects will be summoned for a hospital visit to perform the gait trajectory, the measurement will take about one hour. The aim is to extract features out of the data that is registrated that can detect and classify PIGD. In order to assess the performance of the subject reliable in the home environment with the sensor configurations, performances must be studied on controlled and known trajectories in advance. Therefore a trajectory is designed in which the likelihood of observing any axial disabilities is increased. The sensors only register movement and do no harm. If experiencing serious difficulties with the trajectories there is a risk of making missteps, entering a freezing condition or in worst case falling. The subjects are recruited from the Parkinson population at the Medical Spectrum Twente, Enschede, the Netherlands.

Study objective

Presence of postural instability and gait dissorder PIGD (gait disorders, balance impairment, falls, fal-related injuries and FOG) are an important and disabling feature of idiopathic Parkinson’s disease (PD) where the level of functional ability is affected and has a significant impact on quality of life. For clinicians, it is currently difficult to adequately estimate the patient’s gait and balance problems in their clinical practice. For most Parkinson’s patients, the clinically based assessment does not adequately reflect their actual balance during daily life as it is only an impression at a given moment.

Study design

All measurements will be done in one time.
Quantification of walking is done by accelerometers and gyroscopes. One triaxiale accelerometer (Dynaport), and five triaxiale accelerometer plus triaxiale gyroscope (Xsens) will be fixed on the body in order to obtain the data. The Dynaport will be fixed only on the lower back as the Xsens sensors all are connected to each other and are placed on the lower back, thigh, shank and both feet.

Furthermore the activities are filmed. The assessment of the clinical state is done by clinical tests UPDRS (part III), Timed-Up-and-Go test, 10.

Intervention

N/A

Contacts

Public
Postbus 50000
J.P.P. Vugt, van
Enschede 7500 KA
The Netherlands
+31 (0)53-487 2841
Scientific
Postbus 50000
J.P.P. Vugt, van
Enschede 7500 KA
The Netherlands
+31 (0)53-487 2841

Eligibility criteria

Inclusion criteria

Parkinson patients, which are confirmed idiopathic PD diagnosis according to the UK Parkinson’s disease society criteria, in stages 1 to 4 in Hoehn and Yahr scale are recruited for the study. The patients must be able to walk independently without walking aids. The age-matched controle group will be able to walk without any visible gait problems.

Exclusion criteria

1. Impairments or diseases other than PD that affect gait or balance (e.g. orthopedic, neurological other than PD);

2. Inability to walk multiple short distances, together totaling approximately half an hour;

3. Dependent on walking aids;

4. Severe dyskinesia;

5. Uncorrected visual disturbance.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2009
Enrollment:	25
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL1938
NTR-old	NTR2056
Other	CCMO ABR-formulier : 30293
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A