Concept and Baseline Characteristics of the PLUTO study: Disease Progression in Patients with Parkinson's Disease Uncontrolled on Oral Medication - a Prospective, Multicenter, Observational Study to Assess Health-Related Quality of Life Over 24 Months in Germany (n=263)

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OBJECTIVE

Parkinson's disease (PD) management often involves prolonged oral therapy with numerous attempts at optimization, potentially delaying the introduction of device-aided therapies (DATs). Early identification of patients inadequately controlled on oral medications is crucial for improving outcomes. The MANAGE PD web-based application offers a standardized method for identifying such patients. The PLUTO study, is a prospective, multicenter, observational study conducted over 24 months in Germany within the NeuroTransData (NTD) network of neurologists. It aims to assess the impact of timely initiation of DATs on quality of life and motor symptom progression in PD patients inadequately controlled on oral therapies as identified by MANAGE PD categories 2 and 3*.

CONCLUSIONS

The PLUTO study investigates the importance of early identification and timely intervention with DATs for PD patients not well-controlled on oral medication.

By documenting disease symptom progression and changes in quality of life, this study analyses the potential benefits of DATs and the role of digital tools like MANAGE PD in optimizing PD management.

This poster highlights the baseline characteristics of the study population and provides an overview of the study design and methodology.

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C. Kaufmann, C. Holland, N. Brehm are employees of AbbVie and may own AbbVie stock.

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INTRODUCTION

Parkinson's disease (PD) is a progressive neurodegenerative disorder characterized by motor symptoms such as tremor, rigidity, and bradykinesia, as well as non-motor symptoms like cognitive impairment and sleep disturbances. Treatment of patients with Parkinson's disease is often characterized by long conventional oral therapy with several insufficient optimization attempts, which can delay the timely referral and initiation of device aided therapies (DATs) which in turn negatively affects the patient's quality of life. Early identification of patients who are inadequately controlled on oral medications is crucial. The web-based application MANAGE PD (Making Informed Decisions to Aid Timely Management of Parkinson's Disease; www.managepd.eu) was developed for this purpose. This validated tool identifies patients that may not be adequately controlled on oral medication and patients who require treatment regimen changes (including evaluation for DATs).

METHODS

Study Design

PLUTO is a prospective multicenter observational study of disease progression in 19 outpatient NTD practices.

Baseline Assesment:

- Inclusion/exclusion Demographic, social, and clinical characteristics incl. comorbiidities of patients



Interims Analysis at month 12

Physician assesment

Primary Endpoint: Change in PDQ-8 of Patients with Parkinson 's disease uncontrolled on current oral medication (MANAGE PD category 2 and 3) from baseline visit to month 24

MANAGE PD UPDRS II (activities of daily life), IV (item 32, 33, 34, 39; off time, on time Dyskinesia)

- PDSS-2 (sleep quality) Hoehn & Yahr stage
 - Changes in PD treatment and reasons for changes or not changing current medication

PDQ-8 (quality of life) TSQM (Treatment Satisfaction Questionarie for Medication) full 14 item

PRO assesment

This figure provides an overview of the baseline assessment and primary endpoint for a study on Parkinson's disease management. It includes details on demographic, social, and clinical characteristics of patients, as well as the primary endpoint regarding the change in PDQ-8 over 24 months. Please note that this figure does not comprehensively include all secondary endpoints of the study.

Baseline Characteristics

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Characteristic	Total N=263				
Age	Mean Age: 73.65 years Median Age: 74.0 years				
Age n (%)	< 65: 43 (16.4) > 65: 220 (83.7)				
Sex, n (%)	Male 166 (63) Female 97 (37)				
PD Duration Since Diagosis, Years n (%)	< 10: 131 (53.7) > 10: 113 (46.3)				
Hoehn & Yahr , Scale: n, (%)	1: 3 (1.1) 1.5: 13 (4.9) 2: 65 (24.7) 2.5: 24 (9.1) 3: 89 (33.8) 4: 54 (20.5)				

MANAGE PD Category	Percentage of Patients
Category 2	52%
Category 3	37%

Measure	Category 2	Category 3
PDSS-2 Mean	16.29	20.66
TSQM-14 Mean	48.98	47.37
PDQ-8 Mean	7.37	9.90
UPDRS Mean	12.08	19.04

Visit 1

Baseline

Visit 2

Visit 3

Visit 4

		After 6 Months	After 12 months	After 18 months	After 24 months
Recording of previous therapy	X				
Therapy & Reasons for termination / change, if applicable	X	Continuously during switch / change of therapy			
UPDRS II	X	X	X	X	X
UPDRS IV (Point 32, 33, 34, 39) (modified version including the number of hours for item 32 and 39)	X	X	X	X	X
Hoehn & Yahr Scale	X	X	X	X	X
Use of MANAGE PD	X	X	X	X	X
PDQ-8	X	X	X	X	X
PDSS-2	X	X	X	X	X
TSQM-14 (through the study period and continuously during switch / change of therapy)	X	X	X	X	X

Abbreviations: DAT = Device Aided Therapies; MANAGE PD = Making Informed Decisions to Aid Timely Management of Parkinson's Disease; PDQ-8 = Parkinson's Disease; PDQ-8 = Parkinson's Disease; PD = Parkinson's Disease; PDRS-2 = Parkinson's Disease; Disease Rating Scale. *Following completion of the MANAGE PD questionnaire patients can be distributed into 3 categories' 1, 2, and 3. Patients in category 1 are controlled on the current treatment regimen and benefits may be obtained from further optimization of oral treatment. Patients in category 3 may not be controlled on the current treatment regimen and may benefit from a device aided therapy.