Multi-center study for the Validation of a new Pain Questionnaire in patients with Parkinson's disease (PD)

Principal Investigator**:**	PD Dr. med. Georg Kägi
Status:	ongoing, recruiting
Project Start:	2017
Project End:	2020
Trial Design/Class:	prospective multi-center validation study of a pain questionnaire with 3 centers/ Class: A
Number of Patient:	100
Centers:	3 centers (Kliniken Valens, Rehabilitationsklinik Zihlschlacht, Kantonsspital St. Gallen)
Sponsor/Partner:	PD Dr. Veit Mylius, Kliniken Valens, Klinik für Neurologie und Neurorehabilitation, Valens, Switzerland
Funding:	Swiss Parkinson Association, Zambon, Mundipharma

Summary:

Pain is a common non-motor symptom associated with Parkinson's disease. The prevalence of these pains increases with disease duration and the occurrence of motor fluctuations in parallel with changes in experimental pain perception. The correct diagnosis of pain is essential for the appropriate treatment of the different PD-associated and non PD-associated pains. Pains deriving from motor fluctuation have to be differentiated within the group of PD associated pains. These pains responding to dopaminergic medication further respond very well to deep brain stimulation, whereas other PD related pains not associated with motor fluctuations need a dedicated treatment (e.g. neuropathic pain).

Therefore a pain questionnaire was designed, which was published in 2015 but has not yet been validated. The validation of the questionnaire will not only provide information on the suitability of the questionnaire, but also on clinical relevance, influencing factors and quality of life, and will allow a better characterization of the respective pain.

Objectives:

Overall Objective:
The hypothesis is that the questionnaire is able to differentiate between PD-associated and non PD-associated pain and differentiates between the different pain types in PD. Therefore, we are going to assess the psychometric properties of the Pain questionnaire and the PD-related Pain Scoring System (PD-PSS).
A further aim is comparing the pain ratings with the NFR threshold as objective marker of pain sensitivity.

Primary Objective:
The primary objective is the Validation of the pain questionnaire.

Secondary Objectives:
The different pain types occurring in PD will be described by using descriptive statistics.
The influence of mild cognitive impairment will be assessed by the comparison of the pain data with the MOCA.
PD-associated and non PD-associated pain will be compared.
The pain ratings will be compared with the pain reflex (NFR) threshold in part of the patients.