Translation of research into the development of a commercial PD fluid

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Background

Adequately powered trials on novel PD fluids are lacking, due to recruitment difficulties. The most feasible design for a trial of a novel PD fluid includes simulations on computer models assessing the effects of the introduction of a composite outcome ("MAPE") covering major adverse peritoneal events (peritonitis, technique failure, and membrane deterioration).

Objective

Our aim is to facilitate the development of a novel commercial PD fluid in a typical private sector research approach, by designing a trial that optimizes the assessment of relevant outcomes in PD patients. Clinical and patient-reported outcomes related to these complications will be analyzed from data of the existing patients' cohorts of the Medical University of Vienna.

Methods

This study will be conducted on adult patients with end-stage kidney disease undergoing PD, in Vienna's General Hospital during 2020 – 2023. PD trials will be modeled with well described cohorts to assess effects of innovative trial designs (adaptive designs, composite outcomes) on trial performance.

A systematic review on the membrane function will serve as a base for defining peritoneal membrane deterioration.

For evaluating patient-reported outcomes, a qualitative research approach through semi-structured interviews with patients will be used, and a content analysis will be performed.

Expected results

Based on the systematic review, structured interviews with patients and modelled data using the cohort of patients in Vienna with major adverse peritoneal events ("MAPE") will be appropriately defined. Development strategies for a commercial PD fluid will be optimized by designing "the optimal PD trial".

Fig. 1. Workflow and interdisciplinary integration for designing an optimal PD trial.

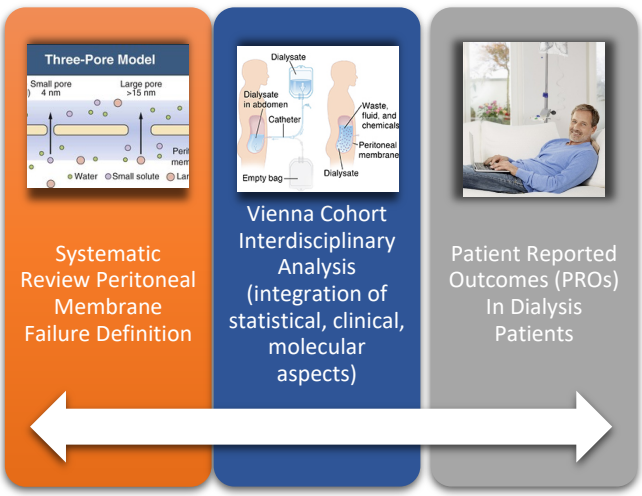
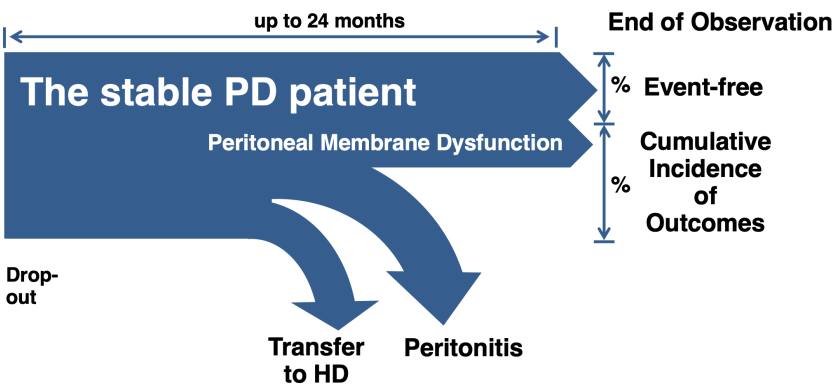


Fig. 2. Implementing MAPE as a composite endpoint into PD Trials.*



Modified by Aufricht A. From Boehm M et al, Perit Dial Int 2019

Conclusion

This study will help to understand and properly design an optimal trial for the assessment of effectiveness, efficacy and safety of a novel PD fluid, through quantitative analysis and qualitative description of PD patient preferences.

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