

# Pre-Odyssey study: an initiative of the Portuguese Society of Nephrology Board

## Estudo Pré-Odissey: uma iniciativa da Direção da Sociedade Portuguesa de Nefrologia

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### ■ OBJECTIVES AND STUDY DESIGN

Pre-Odyssey is an observational study of practice patterns and clinical outcomes in chronic kidney disease patients not on dialysis, promoted by the Portuguese Society of Nephrology. All hospital units in Portugal with a pre-dialysis outpatient clinic are invited to participate in this study.

The primary objectives of this study are the evaluation of the impact of demographic data, co-morbidities and clinical practice patterns on patient outcomes: dialysis initiation or pre-emptive renal transplantation, quality of life, hospitalizations, cardiovascular events and survival. The secondary objectives are the study of the demographic characteristics and the prevalence of co-morbidities of this population (diabetes *mellitus*, hypertension, obesity, coronary artery disease, peripheral artery disease, vascular cerebral disease).

The study will be performed in a multicentre prospective cohort based on the collection of observational and longitudinal data of a representative sample of pre-dialysis patients. The study population will include patients aged 18 years or older with an estimated glomerular filtration rate lower or equal to 60mL/min. This study will have a minimum duration of 1 year and a maximum duration of 5 years, depending on the success of our annual fundraising.

The study is observational and will not alter the clinical management of patients. Data will be collected from medical records and will not require direct contact with patients. The estimated sample size for this study is a total of 1500 patients (stage 3-a: 300 patients, stage 3-b: 400 patients, stage 4: 500 patients and stage 5: 300 patients). All patients need to sign a written informed consent form.

Data will be collected in web-based forms. Each investigator will have a unique login to enter the system. The system will generate automatically an identity number. This study has already been approved by the National Committee for Personal Data Protection (CNPd, Comissão Nacional de Proteção de Dados). The proportional inclusion of patients will be monitored by the entity that has built the electronic case report form (CRF) and that will provide the logistic support for the implementation and statistical evaluation of this study.

### ■ PRIMARY AND SECONDARY ENDPOINTS:

The rationale for this study was based on the classification of endpoints by the KDIGO (Kidney Disease: Improving Global Outcomes) guidelines 2009. Mortality,

cardiovascular disease events, hospitalizations, quality of life (evaluated by the Portuguese validated SF-12 query) and initiation of dialysis or pre-emptive transplantation will be the primary endpoints of this study, defined as those endpoints with a direct importance to patients. Evaluation of vascular calcifications by plain X-ray is considered to be an intermediate endpoint. Biochemical endpoints, as well as vascular calcifications evaluation, are not validated surrogate endpoints for hard clinical events. A list of such exams is suggested in this study, but its complete evaluation is not compulsive, depending on the interest of the individual investigator and according to the patient's desire. However, due to the clinical importance and the low cost of the evaluation of the fractional excretion of phosphate (FEP), we hope to succeed in the universal assessment of this value. In a group of 120 Portuguese patients, it has been verified a high correlation of FEP with FGF23 and an independent association of FEP with cardiovascular events (unpublished data). Fractional excretion of phosphate will be automatically calculated with the formula  $(\text{PO}_4\text{UxCrP})/(\text{PO}_4\text{PxCrU})$ . This study will represent a unique opportunity to assess this independent association and its potential clinical interest in (Chronic Kidney Disease (CKD) patients not on dialysis. The FEP will be evaluated in fasting conditions with the simultaneous collection of P and Cr in blood and in urine samples, after discarding overnight urine. In each hospital participating in this study it is also previewed and allowed to collect and store at -70°C plasma and serum samples from each patient. These samples will subsequently be transferred to a central unit.

## ■ ELECTRONIC CASE REPORT FORM (CRF)

The electronic CRF will be accessible in [www.spn-preodyssey.com](http://www.spn-preodyssey.com) with a personal password that will be provided by the logistic support team. The protocol of the study, the informed consent text and the SF-12 query are available to be printed in this site.

The baseline evaluation will include demographic data, anthropometric measures (weight, height and waist circumference), aetiology of CKD, co-morbidities, blood pressure and serum and urine analyses. The quality of life will be assessed with the Portuguese validated version of the SF-12 query. Yearly observations will repeat the baseline procedures with addition of the outcomes evaluation (quality of life, hospitalization, cardiovascular

events). Discontinuation from the study will be due to withdrawal, or loss to follow-up, or death, or dialysis initiation, or pre-emptive renal transplantation.

Each investigator will have a unique login to enter the system.

## ■ ORGANIZATION

There is a national coordinator and one local investigator for each hospital that has accepted to participate in the study. At this moment, the study protocol has already been submitted and accepted by all the local ethics committees. The role of the local investigator will be a relevant one to maintain local implementation of the study and resolution of the expected difficulties. When necessary, the logistics support team will be contacted for the resolution of problems or clarification of any doubts that may arise.

## ■ CONCLUSION

Pre-Odyssey will be a useful tool to evaluate the Portuguese pre-dialysis reality. The success of this study will depend on the generous contribution and enduring persistence of the individual nephrologist. We hope that this initiative will be able to generate a significant adhesion of the Nephrology community.

## References

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