Study title	An observational study to evaluate the quality of life of patients treated with phytotherapy or alpha-blockers for benign prostatic hyperplasia (PERQOL).
Disease 	Benign Prostatic Hyperplasia (BPH).
Treatment(s) observed 	Phytotherapy and alpha-blockers.
Participants 	Patients with moderate to severe lower urinary tract symptoms (LUTS)/ benign prostatic hyperplasia (BPH) initiating treatment with phytotherapy or alpha-blockers.
Study dates 	From June 2022 to February 2024 (anticipated).
Study Locations 	France, Spain.
We do research to improve patient care. By participating in an observational study, one helps to answer important scientific questions for the benefit of all.	

This document is a brief summary of a clinical study protocol. It is written in plain language for the general public, providing answers to the following questions:

- What is the purpose of the study?
- What are the objectives of the study and how are they evaluated?
- How is the study conducted?
- Who can take part in the study?

What is the purpose of the study?	Benign prostatic hyperplasia (BPH) is a very common disease of aging men (over half of the population concerned after 50 years). In some cases, BPH induces urinary discomfort and disturbances called lower urinary tract symptoms (LUTS). BPH may also be associated to sexual dysfunction. BPH can have a marked effect on patient's quality of life (QoL), particularly when symptoms are moderate or severe. In this context, the purpose of PERQOL, a prospective and observational study, is to assess the impact of LUTS/BPH treatment on patients' QoL and sexual function using dedicated questionnaires.
What are the objectives of the study and how are they evaluated?	The primary objective of PERQOL is to describe the change in QoL of patients receiving treatment for LUTS/BPH (phytotherapy or alpha-blockers) between the beginning of the study and the 6 months of use through a questionnaire. The secondary objectives of PERQOL are to: • Describe demographic and clinical characteristics of patients receiving treatment for LUTS/BPH by collecting data such as age, comorbidities, concomitant treatments, initial treatment(s) for LUTS/BPH… • Describe urinary symptoms of patients receiving treatment for LUTS/BPH. • Describe sexual function and satisfaction of patients receiving treatment for LUTS/BPH.

	• Describe side effects of LUTS/BPH treatments.
How is the study conducted?	This is a prospective, observational study, conducted in France and Spain. Any patient with moderate to severe LUTS/BPH initiating treatment with phytotherapy or alpha-blockers will be invited to participate. Each site will enroll the same number of patients starting phytotherapy and starting alpha-blockers. Overall, 314 patients should be included in the study. Visits will be scheduled as per routine practice. Study questionnaires will be completed by patients at study entry, after 3 months, and 6 months of treatment. No specific medical procedures or in-person clinical visits beyond routine care will be required for this study.
Who can take part in the study?	To be part of the study, patient must fulfill several conditions including the following: • Male patient, age ≥ 40 years at the time of enrollment. • Patient diagnosed with moderate to severe LUTS/BPH. • Patient initiating a first-line phytotherapy or alpha-blockers treatment for LUTS/BPH in monotherapy. • Provided informed consent or non-opposition to study inclusion (only for Spain). • Patient who did not undergo prostate surgery or urinary tract surgery. • Patient not diagnosed with one or several other diseases involving urinary function or prostate. • Patient not diagnosed with BPH with complications (recurrent urinary tract infection, recurrent acute urinary retention, bladder calculus, bladder diverticulum, hydronephrosis, overflow incontinence, recurrent hematuria, obstructive renal failure). • Not participating in interventional trial on any investigation drug at time of inclusion • Not under treatment of the urinary functions

Clinical Study identification	
Protocol Number	NIS13199
Protocol Version	2.0 dated 19 May 2022
Full study title	A 6-months prospective, observational study to evaluate the quality of life of patients treated with phytotherapy or alpha-blockers for benign prostatic hyperplasia.
Registry ID	Not Applicable (NA)

Who sponsors this study?	
Name and contact details of the sponsor	Pierre Fabre Médicament Les Cauquillous 81500 Lavaur-France .

Additional Information

Glossary	
Prospective study	Study where researchers will follow and observe a group of subjects over a period of time to gather information and record the development of outcomes
Phytotherapy	Phytotherapy is the use of plant-derived medications in the treatment and prevention of disease.
Alpha-blockers	These drugs help lower blood pressure but also may be used to ease symptoms of an enlarged prostate.