

## Lay Protocol Synopsis

<b>Lay language title</b>	Observational study to understand how treatments for benign prostatic hyperplasia affect men's quality of life – PERQoL study
<b>Full study title</b>	A 6-months prospective, observational study to evaluate the quality of life of patients treated with phytotherapy or alpha-blockers for benign prostatic hyperplasia – PERQoL study
<b>Registry Number</b>	NCT07144709

### 1 What is the reason for the study?

An increased volume of the prostate is a common condition in older men. This is named “benign prostatic hyperplasia”. It is not cancerous, but it affects more than half of men over 50 years. It is a chronic condition that may progress over time if left untreated.

Sometimes, it causes urinary problems, known as lower urinary tract symptoms, such as:

- frequent urination: especially noticeable at night (nocturia)
- urgency: a sudden, strong need to urinate
- weak urine stream: difficulty starting urination or a stream that stops and starts
- incomplete emptying: feeling like the bladder isn't completely emptied after urination
- dribbling: post-urination dribble

Other possible symptoms include:

- straining: effort needed to begin urination
- intermittency: stopping and starting again several times while urinating.

These symptoms can vary in severity and may not all be present in every individual.

A benign prostatic hyperplasia can also be linked to issues with sexual function.

When the symptoms are moderate or severe, they can significantly affect a man's quality of life. Several treatments can be prescribed to improve symptoms, including phytotherapy or alpha-blockers. Phytotherapy drugs are plant-based medicine. Alpha-blockers are medicines that help lower blood pressure but are also used to ease benign prostatic hyperplasia symptoms.

This study aims to understand the impact of treatments for a benign prostatic hyperplasia on men's quality of life, including their sexual health.

### 2 What are the objectives of the study?

The main objective of this study was to observe how men's quality of life changed over a six-month period while they were receiving treatments (phytotherapy or alpha-blockers) for a benign prostatic hyperplasia. The quality of life was measured using a questionnaire completed by treated people.

The study also aimed to describe:

- the characteristics of men (such as age, sex, and medical details)
- the urinary symptoms using a questionnaire
- the sexual function and satisfaction using a questionnaire
- any side effects from the treatments, meaning unwanted health problems that might be related to the medicine used.

### 3 How is the study conducted?

This was an observational study. This means doctors watched what happened as part of normal care, without changing or influencing treatment choices.

This study took place in general medical practices in France and Spain.

Male with moderate to severe urinary problems linked to benign prostatic hyperplasia, who started treatment with either phytotherapy or alpha-blockers, were invited to participate. People followed their usual care. They filled out quality of life, urinary symptoms and sexual health questionnaires during the study.

No extra tests or visits were required for the study.

#### 4 Who can take part in the study?

The following people could participate in the study:

- Men aged 40 or older at the time of inclusion
- Diagnosed with moderate to severe urinary issues linked to benign prostatic hyperplasia
- Starting first treatment with either phytotherapy or alpha-blockers, using only one type of treatment
- Agreed to participate and allow their data to be used according to local rules
- With no previous prostate surgery or urinary tract surgery
- Not diagnosed with other diseases affecting urinary function or prostate
- Not having serious complications, such as repeated urinary infections or other major problem
- Not participating in another study
- Not receiving treatment for urinary functions.

#### 5 What are the study treatments and how are they administered?

The study did not provide, request, or require any specific or experimental treatment.

Doctors chose the treatment, phytotherapy or alpha-blockers, as part of normal medical practice.

The study simply collected information about the treatment chosen and about what happened after the treatment began.

#### 6 Ethical considerations

The study was carried out in accordance with ethical guidelines and research regulations. It began only after getting official approval. People agreed voluntarily to take part in the study.

#### 7 What are the possible benefits and risks in taking part in the study?

Taking part in this study was voluntary and had no impact on the treatment.

There were no additional risks or no direct benefit for participants. However, the study's findings could contribute in improving the knowledge of treatments for a benign prostatic hyperplasia.