

Lay Protocol Synopsis

Lay language title	Observational study to understand how treatments for benign prostatic hyperplasia (non-cancerous enlarged prostate) affect men's quality of life – PERQoL study
Full study title	A 6-month prospective, observational study to evaluate the quality of life of patients treated with phytotherapy or alpha-blockers for benign prostatic hyperplasia – PERQoL study
Registry Number	NCT07144709

1 What was the reason for the study?

An increased volume of the prostate, called enlarged prostate, is a common condition in older men. This is called “benign prostatic hyperplasia”. It is not cancerous, and it affects around half of men over 50 years of age. 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, including walking at night to urinate (nocturia)
- urgency: a sudden, strong need to urinate
- weak urine stream: difficulty starting urination or a stream that stops and starts
- incomplete emptying: feeling that the bladder has not completely emptied after urination
- dribbling after urination

Other possible symptoms include:

- straining: needing to make an effort to begin urinating
- intermittency: stopping and starting again several times while urinating.

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

Benign prostatic hyperplasia can also be associated with problems affecting 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-blocker. Phytotherapy drugs are plant-based medicines. Alpha-blockers are medicines that relax the muscles around the prostate and bladder opening, making it easier to urinate.

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

2 What were 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-blocker) for a benign prostatic hyperplasia. The quality of life was measured using a questionnaire completed by men participating in the study.

The study also aimed to describe:

- the characteristics of the participants, such as their age 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 was the study conducted?

This was an observational study. This means doctors observed 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-blocker, were invited to participate. Participants continued their usual care. They completed questionnaires about their quality of life, urinary symptoms and sexual health during the study.

No extra tests or visits were required for the study.

4 Who took part in the study?

The following people could participate in the study:

- Men aged 40 or older at the time of inclusion
- Men diagnosed with moderate to severe urinary disorders linked to benign prostatic hyperplasia
- Men starting first treatment with either phytotherapy or an alpha-blocker, used on its own
- Men who agreed to participate and to the use of their data according to local regulations
- Men who had not undergone prostate or urinary tract surgery
- Men who had no other diagnosed diseases affecting urinary function or prostate
- Men who had no serious complications, such as repeated urinary infections or other major urinary problem
- Men who were not participating in another study
- Men who were not receiving other treatment for urinary functions.

5 What were the study treatments and how were they administered?

The researchers did not assign or require any specific or experimental treatment.

Doctors chose the treatment, as part of routine medical practice: phytotherapy or alpha-blocker.

The study collected information about the treatment chosen and about what happened after 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 were 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 benign prostatic hyperplasia.