Lay Summary of Study results

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
Therapeutic area	Urinary system
Disease	Benign prostatic hyperplasia
Study Phase	Real-Word-Evidence study
Final version	31 July 2026

This document is a summary of the study results and conclusions written for the public and for the people who took part in the study.
This summary was finalized on 31 July 2026.
The information in this summary does not include additional information available after this date.

Pierre Fabre Pharmaceutical Group extends its sincere gratitude to everyone who participated in the study. Your involvement is greatly appreciated.

THANK YOU

We hope this document helps you better understand your key role in medical research.
If you have any questions or would like more information about the study results, please do not hesitate to reach out to your doctor or the staff at your study site.

Please note that:

- These are the results from all the participants combined. The individual results of each participant might be different and are not in this summary.
- This summary reflects the results of one single study and other studies may show different results.

Specific terms used in this lay summary may be found in the Glossary of Pierre Fabre

You can click below to find the following information:

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.

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.

2 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.

3 When and where was the study conducted?

The study took place in general medical practices in France and Spain, from June 2022 to July 2024.

Overall, 288 participants took part in the study:

Country	Number of participants
France	205
Spain	83

4 Who took part in the study?

Which participants took part 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.

How many participants took part in the study?

A total of 288 men took part, of whom 268 were included in the analysis.

How old were the participants?

Most participants were over 55 years old (86%). The average age was 66 years old.

5 What were the study treatments?

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 What were the adverse events and the side effects?

What adverse events did participants have?

Participants can have unwanted health issues while receiving treatment during the study. These health issues may or may not be caused by the treatments. They are called adverse events.

Of the 268 participants, 19 had at least one adverse event: 6 in the phytotherapy group and 13 in the alpha-blocker group.

What side effects did participants have?

Side effects are the adverse events considered to be related or possibly related to the medicine used, in this case phytotherapy or alpha-blocker.

8 participants reported at least one side effect: 3 in the phytotherapy group and 5 in the alpha-blocker group. They all stopped the treatment because of these side effects.

None of these side effects was serious*.

* A side effect is serious when:

- It results in death,
- It puts life in danger,
- it results in hospitalisation or prolongs it,
- It causes lasting problems,
- It results in health problems in babies or foetus, or,
- It is considered medically important.

Participants	**Phytotherapy (out of 142 participants)**	**Alpha-blockers (out of 126 participants)**
Participants who had side effects	3 (2%)	5 (4%)
Participants who stopped the treatment because of side effects	3 (2%)	5 (4%)

= participants

The tables below show the side effects reported in the study.

Side effect	**Phytotherapy (out of 142 participants)**
Drug ineffective	2 (1%)
Dysuria (painful urination)	1 (1%)
Abdominal pain	1 (1%)
Diarrhea	1 (1%)

= participants

Side effect	Alpha-blockers (out of 126 participants)
Drug ineffective	2 (1%)
Asthenia (unusual weakness or lack of energy)	1 (1%)
Orthostatic hypotension (a drop in blood pressure when standing up, which can cause dizziness)	1 (1%)
Gynecomasty (enlargement of breast tissue in men)	1 (1%)
Retrograde ejaculation (semen enters the bladder instead of leaving through the penis during ejaculation)	1 (1%)
Syncope (fainting)	1 (1%)

= participants

7 What were the study results?

Most participants (84%) completed all planned study visits.
Questionnaire completion rates were over 90% at the start of the study, and over 75% after 6 months.

Characteristics of participants

About 1/3 of the participants were obese.

About 3/4 of the participants had at least one comorbidity. A comorbidity is an additional medical condition that a participant has at the same time as benign prostatic hyperplasia. The most frequent comorbidities were high arterial blood pressure (50%), hyperlipidemia* (45%), and diabetes (26%).

For most participants (62%), less than one month passed between diagnosis of benign prostatic hyperplasia and the start of treatment. At the start of the study, about half of the participants received each of the treatments: 142 of 268 participants (53%) received phytotherapy and 126 of 268 participants (47%) received an alpha-blocker.

* Hyperlipidemia means having high levels of fats, such as cholesterol and triglycerides, in the blood. It can increase the risk of heart disease because these fats can build up in your arteries, making it harder for blood to flow.

Quality of life

Quality of life was measured using the "Benign Prostatic Hypertrophy health-related Quality Of Life" questionnaire which has a maximum score of 90.
A higher score indicates a better quality of life.
From the start of treatment to six months, the median* change in score was:

- +6.7 in the phytotherapy group (median was 42.8 at the start of the study and 49.9 after 6 months)
- +5.7 in the alpha-blocker group (median was 42.7 at the start of the study and 52.4 after 6 months).

* The median is the middle value when results are placed in order. Half of the results are at or below the median, and half are at or above it.

Urinary symptoms

The urinary symptoms were measured using the "International Prostate Symptom Score" having a maximum score of 35.

A higher score indicates worse symptoms.

From the start of treatment to six months, the median change in score was:

- -5 in the phytotherapy group (median was 17 at the start of the study and 12 after 6 months)
- -6 in the alpha-blocker group (median was 18 at the start of the study and 12 after 6 months).

Sexual function and satisfaction

Sexual function and satisfaction were measured using **"**Male Sexual Health Questionnaire" which has a maximum score of 125. A higher score indicates better sexual function and satisfaction.
From the start of treatment to six months, the median change in score was:

- +2 in the phytotherapy group (median was 74 at the start of the study and 79 after six months)
- +0.5 in the alpha-blocker group (median was 76.5 at the start of the study and 76 after six months).

8 Further information

Are there plans for further studies?

No further studies are planned.

Where can you learn more about this study?

You can find more information about this study on this website: www.ClinicalTrials.gov