ISRCTN11815680 https://doi.org/10.1186/ISRCTN11815680

Quality of life study in patients with urinary symptoms related to prostate enlargement and its change over time according to the received treatment

Submission date
29/11/2019

Recruitment status
No longer recruiting

Registration date
22/01/2020

Overall study status
Completed

Last Edited
27/02/2023

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The purpose of the QUALIPROST study is to measure how urinary symptoms related with the prostate enlargement influence the quality of life of the patients and also how the quality of life is improved when these symptoms are treated with different drugs in a current clinical practice.

Who can participate?
Patients of 40 years and over suffering from urinary symptoms affecting their normal life

What does the study involve?
Patients will be treated as usual by their physician. Before the start of treatment and after six months, data will be collected.
To measure the evolution of the symptoms a questionnaire called International Prostate Symptom Score will be used. The quality of life will be also measured by another questionnaire named Benign Prostatic Hyperplasia Impact Index.
Side effects are also collected and studied as it could affect the quality of life when they appear caused by a specific drug.

What are the possible benefits and risks of participating?
Benefits: Participants will be closely followed by their doctor as he/she will collect specific data related to troubles and how they affect quality of life.
Risks: none anticipated.

Where is the study run from?
1. Hospital Universitario Puerta de Hierro Majadahonda, Spain
2. Hospital Universitario Basurto, Spain
3. Hospital Universitari Parc Taulí, Spain
4. Hospital Universitario Puerto Real, Spain
5. Hospital El Pilar, Spain

6. Instituto Urológico Madrileño, Spain
7. Muganix Servicios Médicos, Spain

When is the study starting and how long is it expected to run for?
September 2009 to June 2011

Who is funding the study?
Pierre Fabre Ibérica S.A., Spain

Who is the main contact?
José Manasanch
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
HBP-EPI-2008-01

Study information

Scientific Title
Quality of life evaluation in patients with LUTS/BPH and its change over time in reallife practice according to the different treatments—the QUALIPROST study

Acronym

QUALIPROST

Study objectives
The aim of the study is to investigate the LUTS/BPH patients' quality of life in a 6-month period of follow-up in current clinical practice related to its treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/04/2009, Ethical and Clinical Investigation Committee of Puerta de Hierra Majadahonda University Hospital (Joaquín Rodrigo 2, 28222 Majadahonda, Madrid, Spain; +34 91 191 76 62; secreceic.hpth@salud.madrid.org), ref: 23/2009

Study design
Longitudinal prospective observational multicenter study

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Lower urinary tract symptoms associated with benign prostatic hyperplasia (LUTS/BPH)

Interventions
This open-label study is carried out in urology outpatient clinics. Patients are ≥40 years of age with an International Prostate Symptom Score (IPSS) score ≥8.

As an observational study, investigators can prescribe any of the commercially available treatments according to their current practice or no treatment.
The prescribed drugs were:
Alpha-blockers (mainly tamsulosin, at a dose of 0.4 mg daily)
Finasteride (5 mg/day)
Dutasteride (0.5 mg/day)
Pygeum africanum extract (Tebetane compuesto® at a dose of 60 mg/day)
Hexanic extract of Serenoa repens (Permixon®; at a dose of 320 mg daily)

QoL and symptoms are measured at baseline and 6 months using the Benign Prostatic Hyperplasia Impact Index (BII) and the IPSS

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)

Alpha-blockers (mainly tamsulosin, at a dose of 0.4 mg daily) Finasteride (5 mg/day) Dutasteride (0.5 mg/day) Pygeum africanum extract (Tebetane compuesto® at a dose of 60 mg/day) Hexanic extract of Serenoa repens (Permixon®; at a dose of 320 mg daily)

Primary outcome(s)
Quality of life, measured by means of the BPH Impact Index questionnaire at the time of the patient inclusion and at 6-months of follow-up.

Key secondary outcome(s))
1. Evolution of the LUTS/BPH, using the International Prostate Symptom Score (IPSS) at baseline and at the 6-month follow-up visit
2. Sociodemographic data collected at baseline, including age, weight, and height
Collected at end of study period:
3. Clinical data collected: date of initiation of urinary symptoms, year of LUTS/BPH diagnosis, and severity of BPH according to IPSS score
4. Data on diagnostic tests (digital rectal examination, prostate volume, Qmax, urine analysis, serum analysis, PSA)
5. Treatment received (yes/no, alpha-blockers, 5-alpha-reductase inhibitors, phytotherapy, other)
6. Comorbidities: high blood pressure, diabetes, dyslipidemia, etc., as well as treatment for co-morbidities
7. Side effects associated with treatment were recorded at the follow-up visit
8. Treatment compliance, by means of the Haynes–Sackett questionnaire

Completion date
30/06/2011

Eligibility

Key inclusion criteria
1. ≥40 years
2. Diagnosis of LUTS/BPH
3. IPSS score of ≥8
4. Signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Total final enrolment
1638

Key exclusion criteria

1. Drug treatment for BPH in the 6 months prior to inclusion or currently receive any drug treatment with a known effect on BPH symptoms (such as diuretics, antihistamines, or tricyclic antidepressants) for any length of time in the 4 weeks prior to inclusion
2. Other urinary disorders (prostatitis, urinary incontinence, urethral strictures, or prostate cancer) or previously undergone surgery of the lower urinary tract
3. Neurological, physical or psychiatric disturbances preventing to fill in IPSS and/or BII questionnaires.

Date of first enrolment
01/09/2009

Date of final enrolment
16/12/2010

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitario Puerta de Hierro Majadahonda
Manuel de Falla, 1
Madrid
Spain
28222

Study participating centre
Hospital Universitario Basurto
Avda. Montevideo, 18
Bilbao
Spain
48013

Study participating centre
Hospital Universitari Parc Taulí
Parc Taulí, 1
Barcelona
Spain
08208

Study participating centre
Hospital Universitario Puerto Real
Romería, 7

Cádiz
Spain
11510

Study participating centre
Hospital El Pilar
Balmes, 271
Barcelona
Spain
08006

Study participating centre
Instituto Urológico Madrileño
Av. del Valle, 13
Madrid
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28003

Study participating centre
Muganix Servicios Médicos
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20012

Sponsor information

Organisation
Pierre Fabre Ibérica S.A.

Funder(s)

Funder type
Industry

Funder Name
Pierre Fabre Ibérica S.A.

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2016	29/11/2019	Yes	No
Other publications		22/06/2022	27/02/2023	Yes	No
Other publications		29/09/2021	27/02/2023	Yes	No
Other publications		12/02/2022	27/02/2023	Yes	No
Other publications		09/09/2020	27/02/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes