

TROPHEE - Benign prostatic hyperplasia: management and medical needs not covered in general practice in France

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General

Identification

Detailed name	Benign prostatic hyperplasia: management and medical needs not covered in general practice in France
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Sign or acronym	TROPHEE
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CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL : 909 315
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General Aspects

Medical area	General practice Urology, andrology and nephrology
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Health determinants	Iatrogenic
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Keywords	adherence, observational, quality of life, satisfaction, sexuality
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Scientific investigator(s) (Contact)

Name of the director	Leclerc-Zwirn
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Surname	Christel
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Unit	Laboratoire GSK
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Collaborations

Funding

Funding status	Private
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Details	Laboratoire GSK
Governance of the database	
Sponsor(s) or organisation(s) responsible	LABORATOIRE GSK
Organisation status	Private
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Not-repeated cross-sectional studies (except case control studies)
Database recruitment is carried out by an intermediary	A selection of health care professionals
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	<p>The study will only be performed with general practitioners. This choice is justified by the fact that general practitioners represent the source of most prescriptions in BPH. The study will be proposed to approximately 800 general practitioners drawn randomly from the 1,200 GPs in the Thalès observatory. A participation of 180 doctors is expected.</p> <p>During the three month including periode, the participating doctors will systematically and consecutively include each patient who meets all of the eligibility criteria and will then give the patient a self-completed questionnaire.</p>
Database objective	
Main objective	To describe the general practitioner long term management plan for patients with symptoms of BPH in France
Inclusion criteria	<p>? Patients over 50 years old</p> <p>? Patients with a diagnosis of BPH for at least 1 year</p> <p>? Patients currently treated with at least one of the treatments for symptoms of BPH</p>
Population type	

Age	Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
Population covered	Sick population
Gender	Male
Geography area	National
Detail of the geography area	France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2009
Date of last collection (YYYY or MM/YYYY)	2010
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	1098
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire
Presence of a biobank	No
Health parameters studied	Quality of life/health perception Others
Other (detail)	Adherence (MMAS), Satisfaction (TSQM)
Procedures	

Data collection method	E-CRF and self administrated questionnaire
Participant monitoring	No
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Publication on going
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only