CAPTURE - An Observational study to assess the burden of illness in prostate cancer patients with low to moderate risk of progression

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General

Identification

Detailed name	An Observational study to assess the burden of illness in prostate cancer patients with low to moderate risk of progression
Sign or acronym	CAPTURE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL : 90 93 05

General Aspects

Medical area	Cancer research Urology, andrology and nephrology
Pathology (details)	quality of life
Keywords	prostate, cancer

Scientific investigator(s) (Contact)

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Unit	Laboratoire GSK

Collaborations

Funding

Funding status	Private

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)	Longitudinal study (except cohorts)
Database recruitment is carried out by an intermediary	A selection of health care professionals A selection of health institutions and services
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Subjects with a diagnosis of low-to-moderate risk PCa will be enrolled and recruitment tracked using an Interactive Voice Recognition System (IVRS) to ensure that at least 670 subjects are enrolled and evenly distributed at 134 subjects per country from France, Germany, Italy, Spain and Sweden
Database objective	
Main objective	? To assess the impact of low-to-moderate risk PCa on the subject's QoL and anxiety/depression at diagnosis and within the first year of treatment. ? To estimate health care consumption and utility values within the first year of diagnosis of subjects with low-to-moderate risk PCa. ? To describe the profile and medical management of subjects with low-to-moderate risk PCa from 5 countries in the European Union (EU), (France, Germany, Italy, Spain and Sweden).
Inclusion criteria	1. Demography: Males aged between 50-75 years. 2. Disease characteristics: Gleason score ?7, PSA ? 20, and clinical staging T1c-T2b (according to D'Amico criteria of low-intermediate

	risk [D'Amico, 1998]). 3. Informed consent: Subject is willing and able to provide written informed consent. 4. Literacy: Able to read and write in order to complete the study questionnaires.
Population type	
Age	Adulthood (45 to 64 years) Elderly (65 to 79 years)
Population covered	Sick population
Gender	Male
Geography area	International
Detail of the geography area	France, Germany, Italy,Spain and Sweden
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2009
Date of last collection (YYYY or MM/YYYY)	2011
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	116 (France)
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	Health care consumption and services

	Quality of life/health perception
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Procedures	
Data collection method	This study will utilize 3 QoL and two additional questionnaires as summarized below:? QLQ-C30 and QLQ-PR25.? EQ-5D.? HADS.? Work Productivity Assessment Index (WPAI).Subjects will be asked to complete the questionnaires in the following order: QLQC30/QLQ-PR25, EQ-5D, HADS, and WPAI. The physician will be asked to complete arunning log of Prostate resource usage.
Participant monitoring	Yes
Details on monitoring of participants	3, 6 and 12 months after the first inclusion visit
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