

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