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Observational Epidemiological Study of disease progression and therapeutic approach in prostate Cancer Patients

Submission date
02/06/2014

Recruitment status
No longer recruiting

Registration date
01/08/2014

Overall study status
Completed

Last Edited
25/06/2020

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
The prostate is a small, satsuma sized gland, found between the penis and the bladder. It helps to make semen. Prostate cancer (PCa) is one of the most common cancers in the world. A Spanish epidemiological study in 2010 (a study that looks at patterns, causes and effects of a disease in a population) found that, in Spain, there were 81.82 cases of PCa per 100,000 men and there were 72.40 cases per 100,000 men in Europe as a whole. There are a number of different treatment
options for PCa. These include vigilant monitoring, radical prostatectomy, external radiotherapy, brachytherapy, external radiotherapy combined with hormone therapy, hormone monotherapy, biphosphonates and chemotherapy. Here, we have designed a new epidemiological study to find out the 1, 2 and 3-year survival rate for different PCa treatments for those patients that took part in the 2010 Spanish epidemiological study.

Who can participate?
Patients who had been included in the 2010 Spanish epidemiological study with newly diagnosed PCa.

What does the study involve?
Data for each of the participants in the study is collected for years 2011 to 2013 from their medical records. This is then looked at to find out information on different treatments and their survival rates.

What are the possible benefits and risks of participating?
There are no benefits or risks to participants as this is an observational trial.

Where is the study run from?
The study is run from a total of 25 hospitals that took part in the Spanish epidemiological study in 2010.

When is the study starting and how long is it expected to run for?
January 2012 to March 2015

Who is funding the study?
Astellas Pharma S.A. (Spain)

Who is the main contact?
Dr Bernardino Minana

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
CAP01-11

Study information

Scientific Title
Observational Epidemiological Study of disease progression and therapeutic approach in prostate Cancer Patients: an observational study

Acronym
GESCAP

Study objectives
In order to know the 1, 2 and 3 year survival rate, both biochemical progression-free survival and clinical progression-free survival, and to study the therapeutic approach in PCa patients we designed this Observational Epidemiological Study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Investigation Ethical Committee of the Hospital Virgen de las Nieves de Granada (Spain)

Primary study design
Observational

Study design
Epidemiological observational multicentre national study. Patient data will be collected retrospectively from the medical records.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
This is an epidemiological, observational, multicentre, national study. A cohort of patients diagnosed with PCa in 2010 included in the Epidemiological study of the estimation of the incidence of PCa in Spain - 2010" will be studied. Patient data will be collected retrospectively from the medical records. Thus, data relative to 2011 will be collected during the early months of 2012, while, following the same procedure, data included in the medical records during 2012 and 2013 will be recorded in the study CRF in the early months of 2013 and 2014, respectively. The clinical variables required to determine the biochemical progression-free survival and clinical progression-free survival will be collected in the 3 study reference years: 2011, 2012 and 2013. It is an observational study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Biochemical progression-free survival at 1, 2 and 3 years after being diagnosed in 2010
2. Clinical progression-free survival at 1, 2 and 3 years after being diagnosed in 2010

Key secondary outcome(s)
1. Patients clinical variables at the time of diagnosis associated with the 1 and 3 year survival
2. Therapeutic approach
3. Cancer-specific survival and overall survival

Completion date
01/03/2015

Eligibility

Key inclusion criteria
Patient that was included in the study with code CaP01-10 with newly diagnosed, histopathologically confirmed PCa in any stage, between 1 January and 31 December 2010

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
Patients who have withdrawn their informed consent to take part in the study

Date of first enrolment
01/01/2012

Date of final enrolment
01/03/2015

Locations

Countries of recruitment
Spain

Study participating centre
University Hospital Morales Meseguer
Murcia
Spain
30008

Sponsor information

Organisation
Astelas Pharma S.A. (Spain)

ROR
https://ror.org/01cjash87

Funder(s)

Funder type
Industry

Funder Name
Astellas Pharma S.A. (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2016	25/06/2020	Yes	No
Results article	results	01/07/2017	25/06/2020	Yes	No
Results article	results	01/01/2019	25/06/2020	Yes	No