

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

Submission date 02/06/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/08/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/06/2020	Condition category Cancer	<input type="checkbox"/> 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

Dr Bernardino Minana

Contact details

University Hospital Morales Meseguer

Urology Department

Av Marques de los Velez, s/n

Murcia

Spain

30008

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)

Study design

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

Primary study design

Observational

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