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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
Dr Bernardino Minana

### Contact details
University Hospital Morales Meseguer
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30008

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

## Secondary study design
Multi-centre

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## 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 measure
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

## Secondary outcome measures

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

### Overall study start date
01/01/2012

### 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

### Age group
Adult

### Sex
Male

### Target number of participants
25 centres with 4087 patients

### 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)

### Sponsor details
Parque Empresarial La Finca
Paseo del Club Deportivo, 1, Bloque 14, 2 planta
Pozuelo de Alarcon
Spain
28223

### Sponsor type
Industry

### ROR
https://ror.org/01cjash87

# Funder(s)

### Funder type
Industry

### Funder Name
Astellas Pharma S.A. (Spain)

# Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### 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 |

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| Results article | results | 01/07/2017 | 25/06/2020 | Yes | No |
| Results article | results | 01/01/2019 | 25/06/2020 | Yes | No |