Post-approval observational prospective study to evaluate the prevalence of the metabolic syndrome in prostate cancer patients both before and after a 12-monthtreatment with quarterly LHRH analogue formulations (ANAMET Study)

First published: 04/11/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/38431

EU PAS number

EUPAS7866

Study ID

38431

DARWIN EU® study

No

Study countries

☐ Spain

Study description

This post-approval observational prospective study assesses the prevalence of metabolic syndrome in men with prostate cancer before and after 12 months of treatment with quarterly Luteinizing-hormone-releasing hormone (LHRH) analogues formulations.

Study status

Finalised

Research institutions and networks

Institutions

Ipsen Pharma

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Institution

Multiple centres: 42 centres are involved in the study

Contact details

Study institution contact

Medical Director, Uro-Oncology

Study contact

clinical.trials@ipsen.com

Primary lead investigator

Medical Director, Uro-Oncology

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/10/2008

Actual: 22/10/2008

Study start date

Planned: 10/12/2008

Actual: 10/12/2008

Date of final study report

Planned: 12/11/2013

Actual: 12/11/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Ipsen

Study protocol

A-92-52014-160_CSP_Redacted.pdf(463.88 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The objective of this study was to assess the prevalence of the metabolic syndrome according to the National Cholesterol Education Program (NCEP) Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (ATP III)/NCEP ATP III Panel definition in men with prostate cancer both before and after a 12-month treatment with quarterly LHRH analogues.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post-approval observational prospective study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L02AE) Gonadotropin releasing hormone analogues

Medical condition to be studied

Prostate cancer

Population studied

Short description of the study population

This study will include patients diagnosed with prostate cancer who are scheduled to receiving long-term treatment (12 months) with quarterly LHRH analogues.

All patients will be evaluated by means of the following inclusion and exclusion criteria:

Inclusion Criteria

In order to be eligible for this study, the patients should satisfy the following criteria:

• Give their written informed consent, (personally signed and dated) before starting with any study-related procedures.

• Be 18 years old or over.

• Have a histology-confirmed prostate cancer diagnosis, and be eligible for either continuous androgen deprivation therapy or treatment with LHRH analogues in accordance with the specifications of the relevant data sheets for a period of at least 12 months.

• Have an estimated survival expectancy of at least 12 months in the investigator’s opinion.

Exclusion Criteria

Patients satisfying any one of the following criteria will not be eligible for the study:

• Being administered or having previously been administered with an androgen

deprivation therapy.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Prostate Cancer patients

Estimated number of subjects

539

Study design details

Outcomes

The primary efficacy endpoint was to assess the prevalence of the metabolicsyndrome in accordance with the NCEP ATP III Panel definition in patients with prostate cancer both before and after 12-month treatment with quarterly LHRH analogue formulations. Clinical Identification of the Metabolic Syndrome based on assessments of Risk Factor Levels. Physical exploration: BMI, Blood pressure, Weight and Abdomen perimeter.Laboratory tests: HbA1c, Triglycerides, Total, LDL and HDL cholesterol, PSA, Total testosterone and Fasting glycaemia.

Data analysis plan

Summarized descriptive statistics were provided (number of subjects, mean, standard deviation, median, minimum, maximum) or else frequency counts of the demographic and baseline data regarding the total populations included / treated. A bilateral confidence interval of 90% was calculated for the difference between prevalence rates of the Metabolic Syndrome at study initiation and at study completion according to the Newcombe's method. If, and only if, the upper limit of the confidence interval was lower than the upper limit of the equivalence region <+ 5%>, prevalence after the study would be demonstrated to be no worse than prevalence at study initiation.

Documents

Study results

IPS-TRI-2008-01 ANAMET Report Summary final 1.0_12Feb2013 GEN014_Redacted.pdf(57.5 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No