# 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

**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

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

### Multiple centres: 42 centres are involved in the study

## Contact details

**Study institution contact**

Medical Director, Uro-Oncology clinical.trials@ipsen.com

**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

## ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## 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