

# Post-marketing observational study to prospectively evaluate the prevalence of cognitive changes in patients suffering of PCa before starting and after six months of treatment with LHRH analogues (ANAMEM study)

**First published:** 04/11/2014

**Last updated:** 01/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS7870

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### Study ID

30171

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### DARWIN EU® study

No

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### Study countries

## Study description

ANAMEM was a post-marketing, observational, prospective, multicentre, open-label study for evaluating which proportion of patients with prostate cancer (PCa) were suffering from cognitive changes before and after six months of treatment with Luteinizing-hormone-releasing hormone (LHRH) analogues.

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## Study status

Finalised

# Research institutions and networks

## Institutions

[Ipsen Pharma](#)

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

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

**Institution**

[Multiple centres: 22 centres are involved in the study](#)

## Contact details

### **Study institution contact**

Medical Director, Uro-Oncology [clinical.trials@ipsen.com](mailto:clinical.trials@ipsen.com)

**Study contact**

[clinical.trials@ipsen.com](mailto:clinical.trials@ipsen.com)

### **Primary lead investigator**

Medical Director, Uro-Oncology

**Primary lead investigator**

## Study timelines

### **Date when funding contract was signed**

Planned: 23/11/2010

Actual: 23/11/2010

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### **Study start date**

Planned: 12/12/2010

Actual: 12/12/2010

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### **Date of final study report**

Planned: 10/06/2014

Actual: 10/06/2014

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## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Ipsen

## Regulatory

### **Was the study required by a regulatory body?**

No

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### **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

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

The objective of this study was to assess the proportion of patients suffering from prostate cancer (PCa) who underwent cognitive changes before and after a six-month treatment with LHRH analogues.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Post-marketing Observational Study

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(L02AE) Gonadotropin releasing hormone analogues

Gonadotropin releasing hormone analogues

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**Medical condition to be studied**

Prostate cancer

## Population studied

## **Short description of the study population**

Male adults with prostate cancer diagnosis histologically confirmed who received a Luteinizing-hormone-releasing hormone (LHRH) analogue therapy and who had given their written consent to participate in the study or represented by someone who had given said consent in their name in accordance with local recommendations/requirements.

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## **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)
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## **Special population of interest**

Other

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## **Special population of interest, other**

Prostate cancer patients

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## **Estimated number of subjects**

404

# Study design details

## **Outcomes**

The cognitive changes were assessed by means of five neuropsychological tests: Digit Subtest of the Wechsler Adult Intelligence Scale (WAIS III), Visual

memory test, Line orientation test (Woodward et al.'s abridged version), Matrices (WAIS III) and Mental Rotation of tridimensional objects. Treatment efficacy Prostate-Specific Antigen (PSA) and testosterone levels)

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### **Data analysis plan**

Scores for each single neuropsychological test were calculated at the baseline and at 6 months, and also their corresponding 95% confidence intervals. Additionally the correlations (Pearson Correlation Coefficients) between the baseline period and 6 months were presented for each of the cognitive tests (including the relevant p value). A score above this limit at 6 months was expected to occur less than 5% of the time, and to represent a statistically significant improvement (scores below such limit would mean a significant worsening). The 95% confidence intervals of these proportions were also displayed. In accordance with this, it was also computed the amount of cognitive test having shown significant changes, and so it was calculated the proportion of subjects with at least 1 or 2 or 3 or more cognitive tests (max = 5) with a significant change. Analyses of the subgroups were also carried out to assess whether any different trends had been observed in the subpopulations.

## Documents

### **Study results**

[IPS-TRI-2010-03 SSR final 2 0 30October2014\\_Redacted.pdf](#) (126.85 KB)

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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

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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## **Check logical consistency**

Unknown

# Data characterisation

## **Data characterisation conducted**

Unknown