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

First published: 04/11/2014

Last updated: 01/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/30171

EU PAS number

EUPAS7870

Study ID

30171

DARWIN EU® study

No

Study countries

☐ Spain

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.

Study status

Finalised

Research institutions and networks

Institutions

Ipsen Pharma

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Institution

Multiple centres: 22 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: 23/11/2010

Actual: 23/11/2010

Study start date

Planned: 12/12/2010

Actual: 12/12/2010

Date of final study report

Planned: 10/06/2014

Actual: 10/06/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Ipsen

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 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

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

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.

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

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 efficacyProstate-Specific Antigen (PSA) and testosterone levels)

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)

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

Unknown