Assessment of safety of Diphereline® SR 11.25 mg in Polish patients with prostate cancer (A-38-52014-163)

First published: 12/11/2014

Last updated: 01/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/30162

EU PAS number

EUPAS7938

Study ID

30162

DARWIN EU® study

No

Study countries

☐ Poland

Study description

This national, post marketing multicentre, observational, non-controlled study designed to formally assess the safety of Diphereline® SR during 12-month observation in patients with locally advance or invasive prostate cancer in normal clinical practice. Only patients who started therapy with Diphereline® SRwere considered as the study participants. The study documents (CRF) recorded justification for the prescription of Diphereline® SR, clinical stage (TMN classification) and grade (Gleason score) of prostate cancer, concomitant diseases and medication. The main outcome is the assessment of adverse (AE) or Serious Adverse Event (SAE) and Adverse Drug Reaction (ADR) related to the use of Diphereline® SR recorded during every 3-months visits necessary for Diphereline® SR injection.

Study status

Finalised

Research institutions and networks

Institutions

Ipsen Pharma

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Institution

Multiple centres: 210 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: 01/08/2008

Actual: 01/08/2008

Study start date

Planned: 31/08/2008

Actual: 31/10/2008

Date of final study report

Planned: 30/09/2010

Actual: 30/09/2010

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:

Primary objective: monitoring of the safety of Diphereline® SR 11.25 mg in general practice.Secondary objective: safety in locally advanced and metastatic prostate cancer.

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

(L02AE04) triptorelin

triptorelin

Medical condition to be studied

Prostate cancer

Population studied

Short description of the study population

Patients with locally advance or invasive prostate cancer in normal clinical practice. Only patients who started therapy with Diphereline® SR were considered as the study participants.

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

3000

Study design details

Outcomes

The assessment of adverse (AE) or Serious Adverse Event (SAE) and Adverse Drug Reaction (ADR) related to the use of Diphereline® SR recorded during every 3-months visits necessary for Diphereline® SR injection.

Data analysis plan

Statistical analyses were performed with the use of STATISTICA 8.0 PL software. Distribution of quantitative variables were shown by mean values and standard deviations, and of qualitative variables by absolute and relative frequencies. Medical Dictionary for Regulatory Activities (MedDRA, version not specified) dictionary was used to code separately AE and SAE. The frequency of AE and ADR was calculated for the population exposed for at least one dose of Diphereline ® SR 11.25 mg.

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