A prospective, single arm, non-interventional study to evaluate the extent to which handling errors (HE) lead to Lack of Efficacy (LOE) in patients treated with ELIGARD® in France

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/42056

EU PAS number

EUPAS22475

Study ID

42056

DARWIN EU® study

No

Study countries

France

Study description

This was a non-interventional, prospective study set in routine clinical practice in France. The Drug Safety Officer (DSO) in France was to receive safety information, from a spontaneous report sent from site, regarding the occurrence of a handling error associated with the administration of ELIGARD™, and a local Pharmacovigilance (PV) case was to be created for processing in the safety database according to Astellas internal procedures.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 50 centres are involved in the study

Contact details

Study institution contact

Clinical Trial Registration Department

Study contact

clinicaltrialregistration@astellas.com

Primary lead investigator

Clinical Trial Registration Department

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 11/10/2017

Actual: 11/10/2017

Study start date

Planned: 30/11/2018

Actual: 19/02/2019

Data analysis start date

Planned: 15/11/2020

Date of final study report

Planned: 31/05/2021

Actual: 27/05/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas

Study protocol

7015-ma-3127-fr-clrp-02-disc01-en-final-02_redacted.pdf(712.21 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

The primary objective of the study was to assess the LOE following a handling error, as measured by serum testosterone, in a selected sample of French patients with Prostate cancer (PCa) who have been injected with ELIGARD™ following the handling error (HE) or where the HE occurs during the administration of ELIGARD™.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-interventional, prospective study

Study drug and medical condition

Name of medicine, other

Eligard

Medical condition to be studied

Prostate cancer stage II

Population studied

Short description of the study population

Inclusion criteria:

• All male patients ≥ 18 years old on ELIGARD™ treatment (3-month formulation [22.5 mg] or 6-month formulation [45 mg]), with a reported HE associated with the administration of ELIGARD™.

• Patients who were informed of the study and the investigator did not receive any objection by the patient to collect their data.

Exclusion criteria:

• Any patient/s correctly re-injected with a new dose of ELIGARD™ shortly after the HE and before a blood sample for serum testosterone was taken.

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)

Estimated number of subjects

50

Study design details

Outcomes

The primary objective was to measure the number and proportion of HE associated with confirmed LOE based on the serum testosterone level after the mishandled ELIGARD™ injection.

Data analysis plan

Demographics and baseline characteristics were to be summarized by dose level for the Safety Analysis Set and Full Analysis Set. Descriptive statistics would have included number of subjects, mean/ SD/min/ median/ max for continuous endpoints, and frequency and percentage for categorical endpoints. Number and proportion of LOE cases among HE cases with a corresponding 95% CI were to be assessed. Descriptive statistics were to be presented in summary tables by dose level and total. AEs were to be coded using MedDRA and graded using NCI CTCAE v 4.03. Number and percentage of AEs, SAEs, AEs leading to discontinuation and AEs related to study drug were to be summarized by System Organ Class, Preferred Term and dose level and total. Number and percentage of AEs by severity were to be summarized. All AEs were to be listed. For quantitative laboratory measurements descriptive statistics were to be used to summarize results and change from baseline by time point for each dose level and total.

Documents

Study results

7015-ma-3127-csr-abstract- Redacted.pdf(103.19 KB)

Data management

Data sources

Data sources (types)

Spontaneous reports of suspected adverse drug reactions

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