Observational Study of Patients Treated with New Available Formulation of Enantone in Prostate Cancer (ONE)

First published: 28/03/2019

Last updated: 01/04/2020

Study | Finalised

Administrative details

EU PAS number

EUPAS27547

Study ID

34463

DARWIN EU® study

No

Study countries

France

Study description

This is an observational, non-interventional, national, multicenter, prospective, longitudinal study of patients with prostate cancer. This study will review the medical records of patients to provide knowledge with the new formulation of Enantone in real-life setting and to assess satisfaction of patients and healthcare staff about Enantone. The patients with prostate cancer who are initiating Enantone 3.75 milligram (mg), 11.25 mg, or 30 mg in pre-filled syringe under standard regular care will be eligible for this study. The study will enroll approximately 200 patients. The study will be conducted at 70 investigative sites in France. The overall time to participate in this study is 18 months. Patients will be followed up for up to 6 months after initiation of treatment. (Study was withdrawn prior to enrollment)

Study status

Finalised

Research institutions and networks

Institutions

Takeda

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 70 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Beauval Jean-baptiste

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 25/07/2018

Study start date

Planned: 15/01/2020

Actual: 01/04/2020

Data analysis start date

Planned: 15/04/2020

Date of final study report

Planned: 15/06/2020

Actual: 01/04/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Primary data collection

Main study objective:

The primary objective of this study is to assess treatment satisfaction in patients initiating Enantone new formulation for prostate cancer.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Longitudinal study

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

LEUPRORELIN

Medical condition to be studied

Prostate cancer

Population studied

Short description of the study population

Patients with prostate cancer who are initiating Enantone 3.75 milligram (mg), 11.25 mg, or 30 mg in pre-filled syringe under standard regular care.

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

200

Study design details

Outcomes

The primary outcomes will assess the satisfaction of patients through TSQM. The secondary outcomes will assess the satisfaction of nurses through visual analogue scale (VAS), characteristics of patients, hot flushes, healthcare resource utilization.

Data analysis plan

Descriptive analysis will be performed of all collected data except data collected only for the purpose of data cleaning. Descriptive analysis of

qualitative and ordinal variables will comprise the mean, standard deviation and their confidence intervals as well as the median and range. Univariate analysis will be performed on data from case report form (CRF) and questionnaire.

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

The data will be collected from the investigators in an electronic case report form (eCRF) and Patients satisfaction Treatment Satisfaction Questionnaire for Medication (TSQM) score.

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