Observational prospective study describing the global patient care and follow-up of prostate cancer patients treated with Degarelix (DUO study (Dialogue in Uro-Oncology))

First published: 20/06/2017

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Study Finalised

Administrative details

EU PAS number

EUPAS18906

Study ID

46959

DARWIN EU® study

No

Study countries

France

Study description

The DUO study's main objective is to evaluate, in the real life, the prevalence of cardiovascular comorbidities among prostate cancer patients receiving Degarelix, before treatment. This study will also assess, at the initiation of therapy, the prevalence of osteoporosis, metabolic comorbidities, depression, sexual and geriatric patients suffering from prostate cancer.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 60 centres are involved in the study

Contact details

Study institution contact

Pierre Mongiat-Artus DK0-Disclosure@ferring.com

Study contact

DK0-Disclosure@ferring.com

Primary lead investigator

Pierre Mongiat-Artus

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 05/08/2015

Actual: 11/04/2016

Study start date
Planned: 30/06/2017

Actual: 27/06/2017

Data analysis start date
Planned: 31/03/2019

Actual: 04/03/2019

Date of final study report
Planned: 30/09/2019

Actual: 30/11/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Ferring SAS

Study protocol

000235_Protocol_14FEB2017_Redacted_20MAY2022_Redacted PDFA.pdf (1.74 MB)

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

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:

To describe the prevalence of the cardiovascular comorbidities, at the initiation of Degarelix, in prostate cancer patients.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Post-authorization safety study (PASS)

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L02BX02) degarelix

degarelix

Population studied

Short description of the study population

Inclusion criteria

Only patients who meet all the following inclusion criteria will be considered for inclusion in the study:

• Male aged 18 years or older

• Diagnosed with hormone dependant advanced prostate cancer PCa

• Patient having received an antagonist of GnRH Degarelix prescription

• Agreeing to and capable of completing in French during the visits all questionnaires on the impact of their illness and treatment

• Patients having received oral and written study information, agreeing to the use of his anonymized data, and having signed a written Informed Consent Form.

Exclusion criteria

Patients will not be included in the study if they meet at least one of the following exclusion criteria:

• Patient included in an interventional study assessing treatment for PCa,

• Patient presenting hypersensitivity to Degarelix or one of its excipients,

• Patient treated by other hormonotherapy

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

170

Study design details

Outcomes

A patient will be considered to have cardiovascular comorbidities if he has a history of at least one cardiovascular illness and/or at least three cardiovascular risk factors. - To describe the real life prevalence of comorbidities: Metabolic, osteoporotic, for elderly patients, and for mood and sexual disorders - To

describe the modification of the comorbidities after 6 months (cardiac, metabolic, osteoporotic, geriatric, mood and sexual disorders) - To describe the Quality of Life for prostate cancer patients - To evaluate tolerance (adverse events)

Data analysis plan

The prevalence of cardiovascular comorbidities will be described along with the 95% CI. Note: The method of physician selection will not ensure sample representativeness, and furthermore physicians can refuse to participate in the study. Sample representativeness will thus be determined by comparing the initial sample of the Sponsor’s national database of sites with the sample of active sites. All results should be interpreted cautiously. In addition, as part of an observational study with prospective cohort study evaluated over a 6-months period, it is important to take into account the handling of missing data for the primary endpoint when considering the accuracy of estimation and relevance of the study results. Nonetheless, because the primary objective is evaluated at baseline, this bias should be reduced

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

This study is an observational, longitudinal, pharmaco-epidemiological, multicenter, prospective cohort study.

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