Enzalutamide and Other Androgen Receptor Pathway Inhibitors (ARPIs) in Metastatic Hormone Sensitive Prostate Cancer (mHSPC): A Non-Interventional Center-based Chart Review in Europe (ENHANCE)

First published: 24/10/2025

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000776

Study ID

1000000776

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany

Study description

Given the clinical significance of mHSPC and the availability of multiple ARPIs for treatment, there remains a need to validate and expand upon existing findings through realworld studies in European settings. Therefore, the objectives of this study are twofold: (1) to assess the feasibility and appropriateness of comparing outcomes among mHSPC patients treated with ARPIs, based on baseline characteristics and outcome data availability; and (2) if deemed feasible, to compare real-world outcomes among mHSPC patients treated with different ARPIs based on a center-based chart review study in Europe

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Study status

Ongoing

Research institutions and networks

Institutions

Astellas Pharma Europe Ltd.

Contact details

Study institution contact

Clinical Trial Registration Department
clinicaltrialregistration@astellas.com

Study contact

clinicaltrialregistration@astellas.com

Primary lead investigator

Thomas McLean

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 02/04/2025

Study start date

Planned: 30/11/2025

Actual: 17/12/2025

Data analysis start date

Planned: 31/03/2026

Date of final study report

Planned: 31/07/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas Pharma Europe Ltd

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

9785-MA-3676

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Healthcare resource utilisation

Data collection methods:

Secondary use of data

Study design:

This study will use information collected from medical centers in Europe of men who started ARPI treatment from Jan2020 until about Dec2024. This study is about collecting information only. The individual’s doctor decides on treatment, not the study sponsor (Astellas).

Main study objective:

In Part 1 the main aim is to compare the profile of the men treated with enzalutamide with the men treated with other ARPIs. Information such as the men’s age when ARPI treatment began, the date of prostate cancer diagnosis, previous prostate cancer treatments or procedures, and health status will be collected.

In Part 2 the main aim is to compare how long the men are treated with enzalutamide compared with other ARPIs. Information such as when treatment stops will be collected.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

XTANDI

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

ENZALUTAMIDE

Anatomical Therapeutic Chemical (ATC) code

(L02BB04) enzalutamide

enzalutamide

Medical condition to be studied

Hormone-dependent prostate cancer

Prostate cancer metastatic

Additional medical condition(s)

Metastatic hormone-sensitive prostate cancer (mHSPC)

Population studied

Short description of the study population

Prostate cancer affects the prostate gland in men and needs male sex hormones such as testosterone to grow. Androgen receptor pathway inhibitors (ARPIs) are a type of hormone therapy used to treat men with prostate cancer. They work by reducing the amount of testosterone in the body. The ARPIs are usually given with other prostate cancer treatments.

This study is for men in Europe who are treated with ARPIs for their prostate cancer. The men have metastatic hormone-sensitive prostate cancer (mHSPC). Metastatic means the cancer has spread to other parts of the body. Hormone

sensitive means the cancer needs male sex hormones such as testosterone to grow.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

600

Study design details

Outcomes

Primary

• Baseline characteristics:

Physician characteristics

o Specialty (e.g., urologist, oncologist)

o Practice setting (e.g., academic institution, community practice, private practice)

• Demographics:

o Age at index (i.e., date of treatment initiation with ARPI)

o Country

o Participating any prospective non-interventional studies (yes/no)

• Clinical characteristics as of the index date (if available):

o Year of initial PC diagnosis

o Performance status (e.g., ECOG)

o Comorbidities

o Tumor grade (Gleason score)

o Disease volume status (high/low); type of imaging used (bone scan, CT scan MRI, or PSMA-PET)

o Disease risk status (high/low); type of imaging used (bone scan, CT scan MRI, or PSMA-PET)

o De novo vs. recurrent status

o For recurrent patients

-Prior treatments (surgery/radiation, NSAA)

-Prior exposure to ADT (yes/no)

-Time from definitive therapy to index

o Site of metastasis

-Visceral metastasis (yes/no)

-Liver metastasis in patients with visceral disease (yes/no)

-Bone metastasis (yes/no)

-Lymph node metastasis (yes/no)

-Other metastasis (yes/no)

o PSA value measured closest to and within 180 days prior to index or initiation of ADT, whichever comes first

o Mean/median testosterone measured prior to index (if available)

o Conventional imaging vs PSMA-PET vs both for diagnosis of mHSPC, disease response, and progression monitoring

o Year of ARPI treatment initiation

o Time between mHSPC diagnosis and ARPI initiation

o Time between ADT and ARPI initiation

Data analysis plan

Baseline characteristics will be reported using descriptive statistics, including means (with standard deviations (SDs), medians (with interquartile ranges (IQRs)), minimum and maximum for continuous variables, as well as counts and proportions for categorical variables.

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 source(s)

Other data source

Data source(s), other

Chart Review (Medical Health Records)

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