FUJI study: Follow-Up of Jevtana® in real lIfe

First published: 15/09/2015

Last updated: 24/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10391

Study ID

47140

DARWIN EU® study

No

Study countries

☐ France

Study description

Prostate cancer is the most common cancer in France, it evolves slowly but there is a poor prognosis at the metastatic stage. Several therapeutic strategies are available such as hormonal therapies and chemotherapies. Cabazitaxel is a new taxane that has an European marketing authorization since March 2011

and indicated in the treatment of patients with metastatic castration-resistant prostate cancer previously treated with docetaxel. The availability of this treatment is recent (Dec 2012) and there is only limited data on the use, safety, and effectiveness of cabazitaxel in real-life practice. In this context, French health authorities request a French multicentre observational study. A retrospective cohort will be implemented with 400 patients initiating cabazitaxel from Sept 2013 to Aug 2015, followed 18 months and a prospective cohort with 60 patients initiating cabazitaxel from Mar 2016 to 28 Feb 2017, followed 6 months. The primary objective of the study is to evaluate the overall survival in the whole cohort and by treatment lines. The secondary objectives are to evaluate the safety, quality of life (QoL) and pain in the prospective cohort, to describe analgesic use, the characteristics of the treated study cohort and the conditions of cabazitaxel use in a real-life setting and to evaluate progression-free survival (PFS). The study will be conducted with participation of hospital pharmacists and physicians. A retrospective identification of patients will be performed by pharmacists from hospital pharmacy registers in order to avoid prescriber’s selection. Data collection will be performed by coordinating centre CRAs from the patient's medical records using an e-CRF. The QoL in the prospective cohort will be assessed using the FACT-P QoL questionnaire and pain will be evaluated by the Brief Pain Questionnaire - Short form (BPI-SF), these questionnaires will be completed by patients before each cabazitaxel infusion, up to the last cabazitaxel infusion.

Study status

Finalised

Research institutions and networks

Institutions

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/02/2023

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

Multiple centres: 45 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nicholas Moore

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 06/01/2015

Study start date
Actual: 30/10/2015

Data analysis start date
Actual: 09/06/2017

Date of interim report, if expected
Actual: 28/08/2017

Date of final study report
Actual: 27/03/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Study protocol

FUJI-ENCePP-PROTOCOL comp HAS approved vs amdt 18 mai 2015_avec logo .pdf(1.81 MB)

FUJI-Protocole Amendement N°2.pdf(1.84 MB)

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To evaluate the overall survival of patients treated by cabazitaxel and according to treatment-line

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01CD04) cabazitaxel

cabazitaxel

Population studied

Short description of the study population

Prostate cancer patients initiating cabazitaxel.

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

Estimated number of subjects

460

Study design details

Outcomes

Overall survival is defined as the interval between the date of first administration of cabazitaxel (inclusion date) and the date of death, irrespective of cause, Safety based on data collected through medical file (NCI-CTCAE v4.0 toxicity scale and MEDdRA code), QoL and pain based on FACT-P and BPI-SF questionnaire. Description of analgesic use, patient's characteristics and cabazitaxel use. PFS defined as interval between inclusion date and date of progressive disease (radiological evaluation, RECIST criteria, clinical and biological parameters).

Data analysis plan

A detailed statistical analysis plan (SAP) will be performed before database lock using SAS® software (latest current version). The SAP will be validated by Scientific Committee. Descriptive statistics including mean, median, standard deviation, minimum, and maximum will be presented for continuous variables. For categorial variables, the number of subjects and percentage within each category will be presented. Describing analyses will concern prescriber recruitment, baseline demographic and clinical characteristics at inclusion date, treatment pattern during follow-up after inclusion date, toxicities by patient,

and quality of life, pain and analgesic consumption. Overall and progression-free survival outcomes will be analysed using Kaplan Meier method and median survival will be reported with 95%CI (adjusted on previous treatment). Multivariate analysis will be using the Cox proportional hazard risk model to assess the factors associated with mortality and progression of disease.

Documents

Study results

FUJI-Summary of study results-ENCePP Final Report-20180605 VF.pdf(1.1 MB)

Study, other information

Synopsis FUJI vUK 28-07-2015 clean final version.pdf(514.36 KB)

Synopsis FUJI vUK amendement N°2 version clean 20180110.pdf(599.08 KB)

Study publications

Joly F, Oudard S, Fizazi K, Tubach F, Jove J, Lacueille C, Lamarque S, Guiard E...

Rouyer M, Oudard S, Joly F, Fizazi K, Tubach F, Jove J, Lacueille C, Lamarque S...

Data management

ENCePP Seal

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

FUJI-ENCePP- DOI Form NM signé.pdf(1.68 MB)

FUJI-ENCePP-DOI Form AF 20150915.pdf(844.47 KB)

Composition of steering group and observers

FUJI-ENCePP-Composition steering committees.pdf(73.65 KB)

Signed code of conduct

FUJI-ENCePP-Code of conduct declaration 20150915 .pdf(352.92 KB)

Signed code of conduct checklist

FUJI-ENCePP-Code of conduct 20150915.pdf(1.65 MB)

Signed checklist for study protocols

FUJI-ENCePP- Checklist Protocol 20150915 VF.pdf(409.77 KB)

Data sources

Data sources (types)

Drug dispensing/prescription data

Other

Data sources (types), other

Prospective patient-based data collection, Medical charts, clinic charts, nurses' notes, medical correspondence regarding the human subject, subject progress notes, Pathology reports, Laboratory reports, Study worksheets, Electronic hospital reporting system Questionnaires Quality of life (FACT-P) and Pain (BPI-SF) directly completed by patients

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