Retrospective analysis of safety in elderly metastatic or unresectable BRAF V600 melanoma patients treated with Tafinlar (dabrafenib) plus Mekinist (trametinib) and correlation with clinical features and non-elderly patients

First published: 08/03/2019

Last updated: 02/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/36726

EU PAS number

EUPAS28059

Study ID

36726

DARWIN EU® study

No

Study countries

☐ Spain

Study description

The purpose of this study is to define the real-world care of elderly metastatic or unresectable BRAF V600 melanoma patients treated with dabrafenib and trametinib in Spain, and provide more data regarding safety in this population. The secondary endpoints will also analyze potential confounding factors, as well as exploratory differences on efficacy. This is a non-interventional, national and purely retrospective study based on secondary use of data from individual medical records to evaluate the safety and real-world management of dabrafenib or combination with trametinib in elderly and non-elderly patients with metastatic or unresectable BRAF V600 melanomaThe study includes a selection period of 7 months and a single visit aimed at obtaining the informed consent of patients (when the patient is alive), which will coincide with one of those regularly conducted by patients over their routine follow-up, without interfering with the investigator’ clinical practice.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Hospital Universitario de Torrecardenas Almeria, Hospital Virgen de la Salud, Toledo Toledo, Hospital Nuestra Señora de la Candelaria Santa Cruz de Teneirife, ICO Badalona (Hospital Germans Trias i Pujol) Badalona (Barcelona), Hospital de la Santa Creu i Sant Pau Barcelona, Hospital Universitario Central de Asturias Oviedo, Onkologikoa San Sebastian, Hospital Universitario Marqués de Valdecilla Santander, Hospital Clínico de Valencia Valencia, Hospital Clínico San Carlos Madrid

Contact details

Study institution contact

Novartis Clinical Disclosure Officer

Study contact

Trialandresults.registries@novartis.com

Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/11/2019

Actual: 22/11/2018

Study start date

Planned: 01/03/2019

Actual: 26/03/2019

Data analysis start date

Planned: 15/10/2019

Actual: 09/01/2020

Date of final study report

Planned: 01/09/2020

Actual: 17/07/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Farmaceutica, S.A

Study protocol

CDRB436BES04_11Jan2019_FINAL_Redacted.pdf(598.06 KB)

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

CDRB436BES04,NOV-DAB-2019-1

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of the study is to describe safety and real-world management of abrafenib and trametinib in the elderly (? 75 years old) Spanish population.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective study

Study drug and medical condition

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

DABRAFENIB

TRAMETINIB

Medical condition to be studied

Malignant melanoma

Population studied

Short description of the study population

The study population have been adult patients with metastatic or unresectable BRAF V600 melanoma, who have received at least one dose of dabrafenib combined with trametinib or dabrafenib monotherapy (in case that combination treatment was available and monotherapy was considered a medical decision).
Criteria for inclusion: Patients will be included in the study if all of the following criteria are met:
1. Age≥ 18 years old
2. Stage IIIC unresectable or stage IV melanoma with BRAF V600 mutation
3. Treatment with at least one dose of dabrafenib plus trametinib, or with dabrafenib monotherapy due to clinician decision (safety, contraindications, etc.) at one of the participating study sites. Patients treated in a compassionate use program are eligible following local regulation.
4. Written informed consent following local regulation (if the patient is alive). If the effort to obtain the informed consent is beyond that is reasonable and feasible, then Ethics Independent Committees (EICs) approval must be obtained (as established in local the regulation Orden SAS 3470/2009).
5. Available medical records
Criteria for exclusion: Patients are excluded from participating in this study if

one or more of the following criteria are met:

1. Patients treated with dabrafenib monotherapy before trametinib was available (June 2013).

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

Malignant melanoma patients

Estimated number of subjects

205

Study design details

Outcomes

Safety measures and endpoints are as follows, and should be provided in the analysis for patients <75 y.o. and ? 75 y.o. (primary endpoint) separately:- occurrence and intensity (grade CTC-AE v4.03) of adverse events- dose delays, dose adjustments, or treatment discontinuation for the management of adverse events. Secondary efficacy measures and endpoints should be provided in the analysis for patients<75 y.o. and ? 75 y.o.:-Response rate by RECIST (v1.1)-

Progression-free survival-Overall survivalDemographics/clinical characteristics: age, sex, stage of disease, metastatic disease, comorbidities, concomitant medications, ECOG and LDH. Real-world management: line of treatment, discontinuation, etc

Data analysis plan

This study is descriptive in nature and no formal hypotheses will be tested. The first step in the evaluation of the data will be to use standard exploratory and descriptive analyses to gain and understanding of the qualitative and quantitative nature of the data collected and of the characteristics of the sample studied. All data collected and endpoints will be summarized using descriptive statistics in addition to statistical modeling. Absolute and relative frequency distributions of qualitative variables will be presented, as well as mean, standard deviation, median, minimum and maximum valuesof quantitative ones. Ninety-five percent (95%) confidence intervals (CI) will be presented for the main quantitative variables When an inferential analysis is required, parametric tests will be used for continuous variables and nonparametric tests in the case of ordinal or categoricalor nonparametric variables. All hypothesis tests will be two-sided and with a significance level of 0.05.

Documents

Study results

CDRB436BES04_CSR FINAL V17Jul2020_Redacted.pdf(1.83 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

For all variables of interest, data sources will be the patients' medical 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

No