Real-world effectiveness of dabrafenib and trametinib in patients with BRAF-positive melanoma treated in routine Bulgarian clinical practice

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000567

EU PAS number

EUPAS1000000567

Study ID

1000000567

DARWIN EU® study

No

Study countries

Bulgaria

Study description

Real-World Data Analysis of BRAF-Targeted Melanoma Therapy Compared to Clinical Trials Using Danny Platform

Study status

Finalised

Research institutions and networks

Institutions

Sqilline Health

Bulgaria

First published: 01/02/2024

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Institution **Non-Pharmaceutical company**

The Bulgarian National Council on Prices and Reimbursement of Medicinal Products (NCPRMP)

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Alexandra Savova

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/03/2023

Actual: 20/03/2023

Study start date

Planned: 01/01/2018

Actual: 01/01/2018

Data analysis start date

Planned: 07/09/2023

Actual: 07/09/2023

Date of final study report

Planned: 18/12/2024

Actual: 18/12/2024

Sources of funding

- No external funding

Study protocol

Real-world effectiveness of dabrafenib and trametinib in patients with BRAF-positive melanoma treated in routine Bulgarian clinical practice

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:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

To assess the real-world effectiveness of dabrafenib and trametinib in patients with BRAF-positive malignant melanoma in a real-world setting.
Compare outcomes, including overall survival (OS) and progression-free survival (PFS), to pivotal clinical trials (COMBI-d and COMBI-v).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

TAFINLAR

MEKINIST

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

DABRAFENIB

TRAMETINIB

Anatomical Therapeutic Chemical (ATC) code

(L01EC02) dabrafenib

dabrafenib

(L01EE01) trametinib

trametinib

Medical condition to be studied

Malignant melanoma

Population studied

Short description of the study population

The study analyzed real-world data (RWD) consisting of 335 patients who were treated with dabrafenib and trametinib from clinical practice between 2018 and 2022.

Age groups

All

In utero

Paediatric Population (< 18 years)

Neonate

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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)

Study design details

Comparators

COMBI-d: comparing the combination of dabrafenib and trametinib to dabrafenib.

COMBI-v: comparing the combination of dabrafenib and trametinib to vemurafenib.

Outcomes

Clinical Outcomes

Progression-Free Survival (PFS). The median PFS based on RWD is 16.1 (95% CI: NC-NC) months in comparison to 9.3 months from COMBI-d trial and 17.0 (95% CI: NC-NC) months vs. 11.4 months from COMBI-v trial.

Overall Survival (OS). In comparison to COMBI-d, RWD outcomes were overall more favorable: OS for RWD was consistently higher than RCT over the first 24 months. Similarly, in comparison to COMBI-v, RWD outcomes were more favorable: OS was close to or higher than the RCT.

Clinical Benefit Rates (CBR) were comparable: RWD is 84.6% (95% CI: 77.9–89.5) vs. 92% for COMBI-d and 90% for COMBI-v.

Documents

Study publications

Real-world effectiveness of dabrafenib and trametinib in patients with BRAF-pos…

Data management

Data source(s)

Danny Platform

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after data extraction