PGx7607: PGx evaluation of pyrexia by meta-analysis of melanoma subjects from BRF113710, BRF113929, BRF113683, MEK115306 and MEK116513 (202050)

First published: 13/11/2014

Last updated: 02/04/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS7953

Study ID

16873

DARWIN EU® study

No

Study countries

☐ United States

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

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Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/10/2014

Actual: 03/10/2014

Study start date
Planned: 14/11/2014

Actual: 14/11/2014

Date of final study report
Planned: 29/01/2016

Actual: 22/01/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

202050-reporting-and-analysis-plan-redact.pdf (1.84 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Pharmacogenetics study

Data collection methods:

Secondary use of data

Main study objective:

The study objective is to identify germline genetic associations with pyrexia by meta-analysis of subjects treated with dabrafenib or a combination of dabrafenib and trametinib from studies BRF113710, BRF113929, BRF113683, MEK115306 and MEK116513

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Pharmacogenetics study

Study drug and medical condition

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

DABRAFENIB

TRAMETINIB

Population studied

Short description of the study population

Caucasian melanoma subjects treated with dabrafenib or a combination of dabrafenib and trametinib.

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

Melanoma patients

Estimated number of subjects

579

Study design details

Data analysis plan

A meta-analysis will be conducted on Caucasian melanoma subjects from five metastatic melanoma studies (BRF113710, BRF113929, BRF113683, MEK115306, and MEK116513).

Documents

Study results

202050-Clinical-Study-Result-Summary.pdf (41.75 KB)

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

Prospective patient-based data collection

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