PGx447:Exploratory genetic analysis of pazopanib (GW786034) related diarrhea in patient with RCC(VEG102616,VEG105192,VEG107769) (116054)

First published: 02/04/2014

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Study Finalised

Administrative details

EU PAS number

EUPAS6234

Study ID

40739

DARWIN EU® study

No

Study countries

United States

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 08/07/2011

Actual: 08/07/2011

Study start date
Planned: 10/11/2011

Actual: 10/11/2011

Date of final study report
Planned: 30/09/2012

Actual: 22/02/2012

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

veg116054-reporting-and-analysis-plan-redact.pdf (243.24 KB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

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

Pharmacogenetic study

Data collection methods:

Primary data collection

Main study objective:

The objective of this analysis is to investigate if genetic markers from 38 candidate genes or other markers from across the genome are associated with incidence of diarrhoea in RCC patients treated with pazopanib in studies VEG102616, VEG105192 and VEG107769.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Pharmacogenetic study

Study drug and medical condition

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

PAZOPANIB

Population studied

Short description of the study population

The genetic analysis population will consist of subjects enrolled in clinincal studies VEG102616, VEG105192, and VEG107769 who provided written informed consent for genetic research, provided a blood sample for genotyping and were successfully genotyped for at least one of the genetic markers under study, have valid phenotype data and pass subject QC.

a. Subject number includes only those who received pazopanib.
b. Subjects provided informed consent and a blood sample for pharmacogenetic research. The clinical data used in this analysis were from the April 2008 data cut-off for VEG102616 and the May 2008 data cut-off for VEG105912 and VEG107769.
c. VEG107769 was an open-label extension to VEG105192 providing the option for patients who developed progressive disease while on placebo to receive pazopanib treatment.

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)

Estimated number of subjects

397

Study design details

Outcomes

The primary endpoint is the diarrhoea outcome status defined as case or control, The secondary endpoint is diarrhoea toxicity grade levels from 1 to 5 and grade 0 for the controls, defined as an ordinal categorical variable.

Data analysis plan

The Case-Control analyses will be performed on the binary outcome measure (diarrhoea status), using logistic regression analysis, the ordinal data analyses will be performed on ordinal categorical diarrhoea toxicity grade levels, using proportional odds model, if the marker meets the p-value threshold for suggestive evidence in the primary anlaysis.

Documents

Study results

116054 results summary.pdf (118.36 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

No