PGx6652: Genetic Evaluation of Pazopanib –Related Hepatotoxicity (117365)

First published: 02/04/2014

Last updated: 29/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6189

Study ID

16864

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

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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: 02/11/2012

Actual: 02/11/2012

Study start date
Planned: 16/11/2012

Actual: 16/11/2012

Date of final study report
Planned: 31/07/2014

Actual: 20/05/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

veg117365-reporting-and-analysis-plan-redact.pdf(316.43 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

Pharmacogenetics study

Data collection methods:

Secondary use of data

Main study objective:

The objective is to identify genetic markers associated with pazopanib-related hepatotoxicity

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

PAZOPANIB

Population studied

Short description of the study population

Patients with pazopanib-related hepatotoxicity who were evaluated for biomarkers.

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

1000

Study design details

Outcomes

Occurance of serious liver injury, maximum ALT measured within the on-therapy window, and time-to-event defined as the time from initiation of pazopanib treatment until the first on-therapy event

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Data analysis plan

For the candidate gene analysis, association between candidate gene alleles/genotypes and the case/control endpoint will be tested using the logistic

regression analysis with appropriate adjustment of covariates. For the GWAS analysis, association between the continuous form of endpoints and genetic variants across the entire genome will be tested using linear and Cox regressions.

Documents

Study results

117365-Clinical-Study-Result-Summary.pdf(153.65 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Retrospective analysis of data from clinical studies

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