PGx7610: Genetic Evaluation of Hepatotoxicity in Pazopanib Studies (201761)

First published: 27/08/2014

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Study Finalised

Administrative details

EU PAS number

EUPAS7361

Study ID

16369

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: 27/06/2014

Actual: 27/06/2014

Study start date
Planned: 01/08/2014

Actual: 01/08/2014

Date of final study report
Planned: 31/12/2014

Actual: 17/02/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-201761-reporting-and-analysis-plan-redact.pdf(284.07 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:

To evaluate genetic associations between HLA-B*57:01 and ALT elevationin pazopanib-treated subjects from 23 clinical studies

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 enrolled in any of the 23 clinical studies, who were exposed to at least one dose of pazopanib and gave a sample for genetic analyses.

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

1080

Study design details

Outcomes

Evaluate carriage of a single haplotype (HLA-B*57:01) in all pazopanibtreated subjects from 23 clinical trials for maximum on-treatment ALT using a one-tailed test, Test association between carriage of the HLA-B*57:01 allele, andsecondary measures of ALT elevation, in patients treated with pazopanib, and test association between genotypes at 16 pre-specified SNPs, and ALTelevation, in patients treated with pazopanib.

Data analysis plan

The primary analysis will evaluate carriage of a single allele (HLA-B*57:01) for a single endpoint using a one-tailed test, and will have controlled false positive rate 5%.Secondary analyses of association between HLA-B*57:01 and other endpoints will be for effect size estimation and for exploratory purposes. Significant association with a secondary endpoint, but not with the primary endpoint, would not be considered a strict sense replication of the association observed in the exploratory analysis.For secondary analyses of the 16 SNPs, false positives will be controlled at 5% for the primary endpoint (maximum on-treatment ALT), using a Bonferroni correction for 16 tests. Secondary analyses for these SNPs with other endpoints will be for effect size estimation and for exploratory purposes.

Documents

Study results

gsk-201761-clinical-study-report-redact.pdf(1.45 MB)

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