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

First published: 27/08/2014
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Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/16369

EU PAS number
EUPAS7361

Study ID
16369

DARWIN EU® study
No

Study countries
United Kingdom

Study status
Finalised

Research institution and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Contact details

Study institution contact
GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor
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:
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 data collection

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