Vascular Endothelial Growth Factor Inhibitors and Artery dissections and aneurysms - An analysis of EudraVigilance

First published: 20/01/2021

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Study Finalised

Administrative details

EU PAS number

EUPAS39117

Study ID

39118

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This was a descriptive study of case reports of artery dissections and aneurysms with vascular endothelial growth factor inhibitors using EudraVigilance data.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Pinheiro Luis

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 06/12/2018

Actual: 07/12/2018

Study start date
Planned: 07/12/2018

Actual: 07/12/2018

Data analysis start date
Planned: 07/12/2018

Actual: 07/12/2018

Date of interim report, if expected
Planned: 30/01/2019

Actual: 11/02/2019

Date of final study report
Planned: 13/02/2019

Actual: 18/02/2019

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

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

Case series review of Pharmacovigilance data

Data collection methods:

Secondary use of data

Main study objective:

To identify and characterise case reports of artery dissections and aneurysms with vascular endothelial growth factor inhibitors and to perform a narrative summary of the relevant individual case safety reports

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-series

Study drug and medical condition

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

SUNITINIB

SORAFENIB

PAZOPANIB

LENVATINIB

VANDETANIB

AXITINIB

PONATINIB

REGORAFENIB

CABOZANTINIB

NINTEDANIB

Medical condition to be studied

Aneurysm

Artery dissection

Population studied

Short description of the study population

Case reports of artery dissections and aneurysms with vascular endothelial growth factor inhibitors.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

660

Study design details

Data analysis plan

Descriptive statistics were performed by substance, by class, by indication, by country, by age, gender and by medical history. Boxplots of time to onset were plotted and stratified by type and number of products. Time to onset was calculated by subtracting the start date of reaction to the start date of the medicinal product. An analysis of disproportionality was conducted, stratified by indication and medical history where possible. An individual case safety review was performed. Serious case reports of aneurysm and artery dissections with

negative outcomes that do not have underlying susceptibility reported, i.e. no medical history of vascular disease and/or associated risk factors, were reviewed by two independent investigators. For the purpose of selecting the case reports, different susceptibilities due to age and gender were not considered.

Documents

Study results

VEGFR and Aneurysm - EV analysis - 20190213.pdf(1.22 MB)

Data management

Data sources

Data source(s), other

EudraVigilance

Data sources (types)

Spontaneous reports of suspected adverse drug reactions

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