Risk of anaphylactoid reactions of Iopromide after intra-arterial administration (UVIA Study)

First published: 03/08/2018

Last updated: 01/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/33695

EU PAS number

EUPAS25089

Study ID

33695

DARWIN EU® study

No

Study countries

☐ Germany

Study description

Iopromide (trade name is Ultravist) is on the market for more than 30 years and has been used more than 250 million times as X-ray contrast medium for patients. It is known that Iopromide may cause allergy-like reactions after being injected. With this study researchers want to find out, if the risk of severe allergy-like reactions is lower, when Iopromide will be injected into an artery, compared to the risk after an injection of Iopromid into a vein. To find this out data from four trials on Iopromide that are already completed will be combined and newly analyzed. The database used for this analysis will contain data from more than 150,000 patients.

Study status

Finalised

Research institutions and networks

Institutions

Bayer AG

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Institution

Contact details

Study institution contact

Bayer Clinical Trials BAYER AG

Study contact

clinical-trials-contact@bayer.com

Primary lead investigator

Bayer Clinical Trials BAYER AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 11/12/2017

Study start date

Planned: 30/09/2018

Actual: 12/10/2018

Data analysis start date

Actual: 12/10/2018

Date of final study report

Planned: 30/04/2020

Actual: 11/07/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

19677_Study protocol _V1.0_2018-07-19.pdf(556.46 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

The primary objective is to evaluate the risk of anaphylactoid reactions of Iopromide after intra-arterial administration compared to intravenous administration.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

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

IOPROMIDE

Population studied

Short description of the study population

Patients who received a contrast enhanced x-ray based examination with Iopromide for various clinical reasons. Iopromide was administered either intra-venously or intra-arterially.

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

150000

Study design details

Outcomes

Number of patients with anaphylactoid reactions of Iopromide after administration, Number of patients with anaphylactoid reactions after intra-arterial administration of IopromideNumber of patients with anaphylactoid reactions after intra-venous administration of Iopromide

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Data analysis plan

Statistical analyses will be of exploratory and descriptive nature only. No confirmatory hypothesis tests will be performed. In case that statistical test is performed p-values will be interpreted as a metric for uncertainty thus no adjustment for multiplicity is necessary.

Documents

Study results

EU-PAS_Abstract_study 19677.pdf(56.7 KB)

Study report

19677 UVIA_CSR_v1.0_final_Redacted.pdf(1.06 MB)

Data management

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