Safety profile of Ultravist in patients with different sexes, races and from different countries/regions

First published: 20/06/2022

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Study Finalised

Administrative details

EU PAS number

EUPAS47805

Study ID

47806

DARWIN EU® study

No

Study countries

- [ ] China
- [ ] Germany
- [ ] Korea, Democratic People's Republic of

Study description

The research question of this analysis is to describe the relative risk / odds ratio of HSRs after Ultravist administrations in patients of different sexes, different races (e.g. Asian, White, Black, other, not specified) and in patients from 37 countries or summarized in global regions (e.g. Europe, North America, Asia w/wo China, Africa).

Study status

Finalised

Contact details

Study institution contact

Bayer Clinical Trials BAYER AG clinical-trials-contact@bayer.com

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: 28/03/2022

Study start date

Planned: 30/06/2022

Actual: 30/06/2022

Date of final study report
Planned: 21/12/2022

Actual: 28/03/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer

Study protocol

22133_EU PASS_CSP_redacted.pdf(835.03 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

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To describe the relative risk / odds ratio of HSRs to Ultravist in patients with different sex, race and from different countries/regions.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Nested Case-Control analysis

Study drug and medical condition

Name of medicine, other

Ultravist

Population studied

Short description of the study population

The study population comprised of patients of all age groups received a contrast enhanced X-ray based examination with Ultravist for various indications identified from the four company sponsored non-interventional studies.

Age groups

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

152233

Study design details

Outcomes

HSRs to Ultravist in patients with different sex, race and from different countries/regions. Differences regarding specific HSRs in patient groups

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Data analysis plan

Statistical analysis will be of exploratory nature only. Unadjusted and adjusted odds ratios (ORs) for the risk factors of interest will be estimated. The adjusted ORs will be based on a logistic regression model that includes the predefined

potential confounders.

Documents

Study results

22133_EU PAS Abstract_Redacted_V1.0_2023-03-28.pdf(1.07 MB)

Study report

22133_Study Report_Redacted_V1.0_2023-03-28.pdf(1.44 MB)

Study, other information

22133_CSR_tables_Redacted_for publication_2023-09-19.pdf(2.41 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Case-control surveillance database

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