Safety profile of Ultravist in children and elderly (UV Age)

First published: 23/10/2020

Last updated: 29/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS37597

Study ID

46253

DARWIN EU® study

No

Study countries

Germany

Study status

Finalised

Research institutions and networks

Institutions

Bayer AG

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Bayer Clinical Trials BAYER AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/09/2020

Actual: 31/10/2020

Study start date
Planned: 31/10/2020

Actual: 31/10/2020

Date of final study report
Planned: 31/12/2021

Actual: 02/02/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

21494_CSP_V1.0_2020-09-21_redacted.pdf (710.46 KB)

21494_CSP_V2.0_2021-01-28_Redacted.pdf (352.34 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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

To describe the risk of hypersensitivity reactions to Ultravist in children and elderly patients compared to middle-age adults

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 of all age groups which were referred to a iodine-based contrast-enhanced procedure of any body part. Patients with missing age, sex or who did not receive Ultravist 300 or 370 were excluded.

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

132.850

Study design details

Outcomes

Number of participants with hypersensitivity reactions to Ultravist in children and elderly patients compared to middle-age adults, Profile of HSRs (hypersensitivity reactions) in the three age groups General reported ADR (adverse drug reactions) profile in the three age groups

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Data analysis plan

Cases of hypersensitivity reactions will be identified following a preset case definition. Controls are patients without any adverse event (AE) after the contrast administration. Logistic regression will be used to analyse the data with adjustment for potential confounders: sex, history of adverse reactions, mode of administration etc. The entire planned analysis will be described in a statistical analysis plan, which will be finalized before the analysis starts.

Documents

Study results

21494_EU PAS Abstract_Redacted_V1.0_2022-02-02.pdf (282.87 KB)

Study report

21494_CSR_V1.0_2022-02-02_Redacted.pdf (1.16 MB)

Study publications

Endrikat J, Chernova J, Gerlinger C, Pracz M, Lengsfeld P, Bhatti A, Michel A. ...

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Four company sponsored non-interventional studies with iopromide

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