

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

**First published:** 20/06/2022

**Last updated:** 07/03/2024

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).

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## 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](mailto: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

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### Study start date

Planned: 30/06/2022

Actual: 30/06/2022

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### **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

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**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

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**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.

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### **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)

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### **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)

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### 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](#)

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### Data sources (types), other

Case-control surveillance database

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No