



Observational Study Results Synopsis

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1. Abstract

Acronym/Title	UV Population - Safety profile of Ultravist in patients with different sexes, races and from different countries/regions
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Keywords	Contrast Medium, Radiology, Iopromide, anaphylactoid reactions
Rationale and background	Ultravist is on the market for >36 years and has been administered >315 million times (Dec 31, 2021). While the general safety profile, including relative risk / odds ratio of hypersensitivity reactions has been widely investigated, data is limited with respect to sex, race, and countries/regions.
Research question and objectives	To describe the relative risk / odds ratio of hypersensitivity reactions to Ultravist (Iopromide) with respect to sex, race, and countries/regions.
Study design	Nested Case-Control analysis in a pooled cohort of 4 non-interventional studies with Ultravist
Setting	In this integrated analysis the data of four company sponsored non-interventional studies 'PMS I', 'Ultravist in CT', 'IMAGE' and 'TRUST' were pooled and analyzed.
Subjects and study size, including dropouts	About 132,000 records of patients were expected for evaluation.
Variables and data sources	<p>The outcome variable is the record of at least one hypersensitivity reaction (HSR) per patient (yes/no). The definition for HSR used in this study is preset.</p> <p>The risk factors of interest are sex, race, country, and geographic region.</p> <p>Confounder variables are age, concomitant diseases, pre-treatment (corticosteroids, H1/H2 blocker), dose and</p>



	<p>concentration of iodine, route of administration (intravenous, intra-arterial), previous CM reaction, allergy, asthma.</p> <p>Four company sponsored non-interventional studies with Ultravist.</p>
Results	<p>A slightly higher disposition for HSR is seen in female patients, while no signal is seen for race. UV populations strongly points to country study reporting effects unrelated to the true risk of HSRs.</p>
Discussion	<p>The study adds further knowledge to an already pretty advanced picture. Female gender is albeit not a strong but an independent risk factor for HSR to CM application, while race, at least Asian vs. European and geographical region does not really seem to have a role. However, country specific reporting patterns need to be considered.</p> <p>Given the importance of clinical imaging and the high expectations regarding the safety of a contrast agent any additional information which further details the knowledge of the users on the characteristics of the contrast agents is of value.</p>
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