Science For A Better Life

Clinical Study Synopsis

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The study listed may include approved and non-approved formulations or treatment regimens. Data may differ from published or presented data and are a reflection of the limited information provided here. The results from a single trial need to be considered in the context of the totality of the available clinical research results for a drug. The results from a single study may not reflect the overall results for a drug.

Title	UVIA: Risk of anaphylactoid reactions of Iopromide after intra-arterial administration
Keywords	Contrast Medium, Radiology, Iopromide, anaphylactoid reactions
Rationale and background	The safety profile of Iopromide and all other iodinated contrast media is well understood, there is a continuous discussion pertaining to the nature of anaphylactoid reactions which are unpredictable. Since anaphylactoid reactions are rare only a retrospective analysis on a large database bears the potential of answering this scientific question.
Research question and objectives	Evaluate the risk of anaphylactoid reactions of Iopromide after intra-arterial administration compared to intravenous administration.
Study Design	The study was designed to investigate the risk of anaphylactoid reactions to Iopromide after intra-arterial versus intra-venous administration.
Setting	In this integrated analysis the data of four company sponsored non-interventional studies 'PMS I', 'Ultravist in CT', 'IMAGE' and 'TRUST' were pooled.
Subjects and Study Size, including dropouts	About 122,000 records of patients with intra-venous and approx. 28,000 patients with intra-arterial administration were expected for evaluation.
Variables and Data sources	The primary variables to answer the study objectives were the number and percentage of anaphylactoid reactions which were documented by pooling data of four company sponsored non-interventional studies with iopromide.
Results	Anaphylactoid reactions were significantly more frequently recorded after i.v. than after i.a. administration, 0.7 % vs 0.2%, respectively ($p < 0.0001$). Adjusted Odds ratio (i.a. vs. i.v.) was 0.23 (95 % C.I. 0.16 - 0.32) for all countries together. For China only: 0.22 (0.11 - 0.44); for all countries without China: 0.36 (0.25 - 0.53). The most frequent anaphylactoid reactions were skin reactions (erythema, urticaria, rash), reported in 508/133,331 patients (0.4%), followed by pruritus (n=294; 0.2%), cough/sneezing (n=151; 0.1%) and dyspnea/bronchospasm (n=105; <0.1%). Clinically relevant severe adverse reactions like anaphylactic shock, laryngeal edema and respiratory arrest were recorded once each (Table 5, Figure 2).
Discussion	This study showed anaphylactoid reactions to be significantly more frequent after i.v. than after i.a. administration, 0.7 % vs 0.2% ($p<0.0001$), respectively. This risk difference remained even after adjustment for potential confounders. Also the specific symptoms, i.e., erythema/urticarial/rash, pruritus, cough/sneezing

	and dyspnea/bronchospasm were more often seen after i.v. administration. To the best of our knowledge, this has not been shown before in a large cohort study, and confirms a hypothesis concerning the nature and patho-mechanisms of these reactions.
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