



“...characterize the risk profile of the intravenous immunoglobulin (IVIg) Intratect®”
Bauhofer et al (2014).

References:

Bauhofer, A., Dietrich, R.L. and Schmeidl, R. (2014) Safety monitoring of the intravenous immunoglobulin preparation Intratect® in primary and secondary immunodeficiencies: a prospective non-interventional study. International Journal of Clinical Pharmacology and Therapeutics. October 27th. .

Study characterises risk profile of intravenous immunoglobulin [@ivteam](http://ctt.ec/1GLUS+)
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Abstract:

Objectives: To better characterize the risk profile of the intravenous immunoglobulin (IVIg) Intratect®, a non-interventional study was undertaken to systematically collect large-scale safety information under real-life conditions in patients with primary and secondary immunodeficiency. Secondary objectives were data on treatment modalities.

Methods: A prospective, non-interventional study was performed at 95 centers. Results of an interim analysis are reported here. Intratect® (50 g/L) was administered at the physician’s

discretion. Data were captured from patients with different causes of immunodeficiency (61.5% with malignancy) at routine clinic visits, with a particular focus on the frequency and causality of adverse events.

Results: 1,313 patients were followed for a median of 294 days. At study entry, 836 patients (63.7%) were receiving therapy, most frequently IVIG treatment (37.2%). In total, 21,995 Intratect® infusions were documented (median 11 infusions per patient, median dose 200 mL). Median serum IgG level increased from 5.78 (interquartile range 3.70, 8.87) g/L at month 1 to 6.58 (4.82, 9.48) g/mL at month 12. Altogether, 689 adverse events were collected, irrespective of causality. From these, 225 (32.7%) were assessed as related to Intratect® and thus considered suspected adverse drug reactions (ADRs). Thus, the ADR rate was 1.0% per infusion. Seven ADRs (7/225, 3.1%) were graded serious. In all cases, the patients had recovered or were recovering at the time of reporting.

Conclusions: Use of Intratect® for immunoglobulin substitution in primary and secondary immunodeficiency under real-life conditions is associated with a low rate of suspected ADRs. Serious ADRs are rare and manageable.

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