



A comparison of venous tolerability and injection pain of Propofol diluted in a lipid emulsion and standard Propofol in the induction of anaesthesia

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Background: Pain on injection is the most frequently reported side effect associated with the use of Propofol. Depending on the size of the vein used, up to 90% of the patients complain about pain on injection of Propofol dissolved in a long-chain triglyceride (LCT)-fat emulsion. Various measures have been taken to reduce the pain on injection. The objective of the study was to compare anesthesia induction by means of a new Propofol emulsion (Propofol-®Lipuro 0.5%) and Propofol-®Lipuro 1.0% with regard to venous tolerability and injection pain in children.

Methods: The study was a prospective, monocenter, parallel group, controlled, randomized, single-blind and, regarding the primary endpoint, double-blind ('observer blind') clinical phase III study. Sixty-four children (2-6 years of age) were randomly assigned to one of the following groups: Propofol-®Lipuro 0.5% or Propofol-®Lipuro 1.0%. The primary endpoint of the study was the incidence of spontaneous expressions of pain during Propofol injection assessed by spontaneous expressions of pain. In a subgroup of 21 children triglyceride levels at three defined times (immediately prior to, 3 and 20 after induction of anaesthesia.

Results: As to efficacy, need of Propofol is similar in both treatment groups. Concerning time until absence of winking reflex, similar Propofol dosages in the two groups were required. Injection pain as the primary endpoint in this study was differently distributed in both trial groups with clear advantages for Propofol 0.5%. At least one reaction of pain was shown in 23.3% in the Propofol 0.5% group and 70.0% in the Propofol 1% group. A significantly higher increase of triglycerides three minutes after induction of anaesthesia was seen after administration of Propofol 0.5%. Twenty minutes after Propofol treatment, however, a clear decreasing tendency was observed. Thus, the increase in triglycerides seems to be only temporary.

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