



A multi-center, randomized, double-blind, positive controlled study to evaluate the efficacy and safety of propofol (Propofol-[®]Lipuro) in total intravenous anaesthesia

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Background: Propofol has an excellent anaesthetic outcome and is easily controllable. After administration, both adult patients and children older than 1 month of age could smoothly regain consciousness. While the most common adverse reaction of propofol is pain on injection, the advantage of propofol dissolved in a lipid emulsion of medium and long chain triglycerides is that it can reduce the painful feeling during injection. The objective of the study was to compare the efficacy and safety of Propofol 1% (Propofol-[®]Lipuro 1%) versus Diprivan[®] 1% during the period of total intravenous anaesthesia (TIVA).

Methods: The study was a prospective, multicenter, parallel group, controlled, randomized and double-blind clinical phase III study. 207 patients (18-65 years of age) were randomly assigned to one of the following groups: Propofol-[®]Lipuro 1% or Diprivan[®] 1.0%. The primary endpoints of the study were the time from anaesthesia induction to loss of eyelash reflex and the needed propofol dosage.

Results: There was no significant difference between two groups ($P=0.5255$) regarding time to loss of eyelash reflex (Propofol-[®]Lipuro 1%: 3.69 ± 2.32 min and Diprivan[®] 1%: 3.85 ± 2.05 min). The equivalence could be shown for both groups. The same applies for the propofol dosage for loss of eyelash reflex: Propofol-[®]Lipuro 1%: 76.57 ± 24.08 mg and Diprivan[®] 1%: 81.27 ± 32.29 mg. As compared with Diprivan[®] 1%, Propofol-[®]Lipuro is equally safe and efficacious for induction and maintenance of TIVA. In addition Propofol-[®]Lipuro 1% markedly reduced the incidence of patient injection pain occurrence in 17.31% after Propofol-[®]Lipuro while 32.04% after Diprivan[®] 1%, $P=0.0158$.

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