



Prospective, monocentric, controlled, randomized, double-blind study comparing two different propofol emulsions regarding tolerability and injection pain during induction of anaesthesia in adults

B. Braun Melsungen AG, Hospital Care, Clinical Development

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 adults.

Methods: This is a prospective, monocenter, parallel group, controlled, randomized, double-blind clinical phase III study. 100 patients (between 18 and 80 years of age) are randomly assigned to one of the following groups: Propofol-®Lipuro 0.5% or Propofol-®Lipuro 1.0%. The primary endpoint of the study is the incidence of spontaneous expressions of pain during Propofol injection assessed by spontaneous expressions of pain and a VAS.

Principal investigator: Stefan Soltész, M.D, Klinik für Anästhesie und operative Intensivmedizin, Klinikum Leverkusen, Germany

Status: Publication under preparation

Sponsor: B. Braun Melsungen AG

Register: <http://clinicaltrials.gov/ct2/show/NCT00690495?term=braun+propofol&rank=2>