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CLINICAL TRIAL

Compare the Effect of Propofol vs. "Ketofol" on Hemodynamic Stability During Induction of General Anesthesia

First received on October 31, 2014. Last updated on December 14, 2016.

Purpose

The purpose of this study is to compare the hemodynamic effects of a standardized induction of general anesthesia with either propofol or ketofol in patients with physical status classification ASA 3. The study will be a double blinded, randomized controlled trial (RCT) with two arms of treatment groups. One arm will consist of induction of general anesthesia using a mixture of 1.5mg/kg:0.75mg/kg Propofol/ketamine (ketofol) and the induction dose will be 1.5mg/kg of propofol and 0.75mg/kg of ketamine; the second arm will consist of induction of general anesthesia using propofol 2mg/kg. The primary outcome of the intervention will consist of hemodynamic changes during the first 30 minutes after induction of general anesthesia.

Status	Withdrawn
Condition	Patients With "ASA 3" Designation
Phase	Phase 2
Study Type	Interventional
Study Design	Allocation: Randomized, Endpoint Classification: Efficacy Study, Intervention Model: Parallel Assignment, Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Primary Purpose: Supportive Care
Official Title	A Randomized-Controlled Trial to Compare the Effect of Propofol vs. "Ketofol" on Hemodynamic Stability During Induction of General Anesthesia

Further study details (as provided by National Institutes of Health Clinical Center (CC))

Start Date	January 2015

Detailed Description

The anesthetic agent propofol can result in hypotension when used for induction of general anesthesia. Recent trials suggest that even a short duration of hypotension during induction of anesthesia can

adversely affect organ function and overall outcome.1 To overcome the hypotensive effect of propofol, ketamine, which has sympathomimetic effects, has been combined with propofol to produce a mixture labeled "ketofol", which has been used both for procedural sedation and induction of general anesthesia. Clinical trials have shown that ketofol can attenuate the hypotensive effects of propofol during procedural sedation or induction of general anesthesia in patients whose physical status is 1 or 2 according to the American Society of Anesthesiologists (ASA 1-2), i.e., healthy patients or those with mild-moderate systemic illness.2,3 Clinically, it is important to demonstrate the efficacy of ketofol in attenuating hypotensive effects of propofol in sicker patients, i.e., patients with physical status ASA 3. The purpose of this study is to compare the hemodynamic effects of a standardized induction of general anesthesia with either propofol or ketofol in patients with physical status classification ASA 3. The study will be a double blinded, randomized controlled trial (RCT) with two arms of treatment groups. One arm will consist of induction of general anesthesia using a mixture of 1.5mg/kg:0.75mg/kg Propofol/ketamine (ketofol) and the induction dose will be 1.5mg/kg of propfol and 0.75mg/kg of ketamine; the second arm will consist of induction of general anesthesia using propofol 2mg/kg. The primary outcome of the intervention will consist of hemodynamic changes during the first 30 minutes after induction of general anesthesia. Baseline demographics collected for each patient will include: 1. age 2. sex 3. ASA physical status 4. Hx of HTN 5. Hx of PONV 6. Preoperative pain score The standardized induction of anesthesia will consist of intravenous administration of midazolam 0.04mg/kg, lidocaine 1 mg/kg, fentanyl 1-2 mcg/kg, glycopyrrolate 0.004 mg/kg, an unlabeled pre-prepared, covered syringe which will be prepared by the Yale Anesthesia satellite pharmacist containing either propofol 2mg/kg or a mixture propofol 1.5mg/kg and ketamine 0.75mg/kg, the amount of which will be pre-determined based on the patient weight, and rocuronium 0.6 mg/kg. A backup 10cc syringe of the study drug will be available as well if the initial dose is inadequate. The choice of propofol and ketamine dosing is based on a study cited earlier by Smischney et al in 2012 that addresses ASA 1-2 patients undergoing induction of general anesthesia. Endotracheal intubation will take place after adequate muscle relaxation has been determined using fade of train of four on a nerve stimulator placed over the ulnar nerve. Additional medication to facilitate induction will be used according to the judgment of the anesthesia provider with a backup syringe of the same study drug. Inhalational anesthesia will be administered after confirmation of endotracheal intubation. Treatment of hypotension will be according to the anesthesia provider. Amounts of intravenous fluids as well as doses of vasopressor that are used during induction and in the subsequent 30 minutes after endotracheal intubation will be obtained from the anesthesia record. The first blood pressure (BP) upon arrival to the operating room before any anesthetic medications are administered will be the reference (baseline) blood pressure. BP will be measured every 1 minute from one minute before induction until 30 minutes after endotracheal intubation. The primary outcome of the study will be the number of time points during which the blood pressure was below 20% of the baseline BP. Secondary outcomes will include: 1. Severity of hypotension as determined by the gradient of each blood pressure measurement from the baseline BP. 2. The total dosage of vasopressors administered during induction and up to 30 minutes after endotracheal intubation 3. The total amount of IV fluids administered during induction and up to 30 minutes after endotracheal intubation. 4. The total amount of additional medications used during induction and up to 30 minutes after endotracheal intubation. 5. Total intraoperative as well as postoperative opioid dosage used. 6. Presence or absence of PONV and severity 7. Intraoperative prophylaxis and postoperative treatment of PONV

Eligibility

Minimum Age Eligible for Study:	18 Years
Maximum Age Eligible for Study:	80 Years
Genders Eligible for Study:	Both

Criteria

Inclusion Criteria: - Patients age 18-80 scheduled for elective surgery - Physical status ASA 3. Exclusion Criteria: - Patients with a physical status of ASA 1,2, 4 or 5, - Prior adverse reaction to propofol, ketamine or both

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT02282891

Locations

Yale New Haven Hospital

Facility:	New Haven, Connecticut, 06519, United States

Sponsors and Collaborators

Yale University

More Information

Other Publications

First Received:	October 31, 2014
Last Updated:	December 14, 2016
ClinicalTrials.gov Identifier:	NCT02282891
Health Authority:	United States: Institutional Review Board

ClinicalTrials.gov processed this data on December 21, 2016 Link to the current ClinicalTrials.gov record. (https://clinicaltrials.gov/show/NCT02282891)