ClinicalKey

CLINICAL TRIAL

A Comparison of Ketofol (Ketamine and Propofol Admixture) Versus Propofol as Induction Agents on Hemodynamic Parameters

First received on February 7, 2010. Last updated on November 28, 2012.

Purpose

This is a pilot study to compare the hemodynamic changes that occur during induction with a novel drug combination known as ketofol (propofol and ketamine admixture with that of propofol alone (prototypic anesthesia induction agent). Propofol and ketamine are widely used as induction agents and their effects on patient hemodynamics are well known. Some of these drug-induced hemodynamic changes are undesirable and lead to deleterious effects on patient hemodynamics. We seek to investigate the hemodynamic changes associated with a novel drug combination known as ketofol (ketamine/propofol admixture) during induction and compare them to propofol. If we determine that the changes produced by ketofol are favorable compared with propofol, we then will seek to test its use in the trauma setting in a subsequent randomized controlled trial.

Status	Completed
Condition	Hemodynamic Changes
Phase	N/A
Study Type	Interventional
Study Design	Allocation: Randomized, Endpoint Classification: Pharmacokinetics/Dynamics Study, Intervention Model: Parallel Assignment, Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Primary Purpose: Prevention
Official Title	A Comparison of Ketofol (Ketamine and Propofol Admixture) vs. Propofol as Induction Agents on Hemodynamic Parameters

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

Enrollment	85
Start Date	December 2009

Detailed Description

This is a pilot study to compare the hemodynamic changes that occur during induction with a novel drug combination known as ketofol with that of propofol. Propofol and ketamine are widely used as induction agents and their effects on patient hemodynamics are well known. Many of these drug-induced changes are undesirable and when used alone sometimes lead to hemodynamic effects on opposite ends of the spectrum, ie. hypotension (propofol) and hypertension (ketamine). We will investigate the hemodynamic changes associated with this drug combination referred to as "ketofol" (ketamine/propofol admixture) during induction compared with propofol as the gold standard induction agent used widely in anesthetic practice. If we validate that the changes produced by the ketofol admixture are favorable, we will then test its use in a wider setting of patient populations including emergency department intubations and the trauma setting. Background: Propofol is a non-opioid, non-barbiturate, sedative-hypnotic agent with rapid onset and short duration of action. It possesses many favorable effects such as an antiemetic effect and reliably produces sedation and amnesia (Felfernig Jour of Royal Naval Medical Service, '06; White International Anesth Clinics, '88; Willman Ann of Emer Med, '07). However, there are several undesirable side effects such as cardiovascular and respiratory depression. In addition, Propofol as a sole agent has no analgesic properties. These drug-induced side effects have led to alternative drugs being used with the hopes of a more favorable side effect profile. Ketamine is an example of one such drug. Ketamine is a phencyclidine derivative commonly classified as a dissociative sedative with fairly rapid onset and short duration of action (Felfernig Jour of Royal Naval Medical Service, '06; White International Anesth Clinics, '88; Willman Ann of Emer Med, '07). It causes little or no respiratory and cardiovascular depression and unlike propofol, has pain relieving properties. Ketamine as a single induction agent, however, is limited by emergence phenomena including postoperative dreaming and hallucinations, however these are attenuated by the administration of benzodiazepines. Also ketamine in induction doses 1-4.5 mg/kg can have some undesirable effects on hemodynamics (opposite of propofol) in certain patient populations including ischemic heart disease (IHD), and patients with increases in intracranial hypertension and intracranial pressure (ICP). Effectiveness of the two agents in combination has been recently demonstrated and this new combination could allow a novel induction agent with favorable effects on hemodynamics (Felfernig Jour of Royal Naval Medical Service, '06; Hui Jour of Amer Soc of Anesth, '95; Willman Ann of Emer Med, '07). To date, this combination known as ketofol has been used most extensively for procedural sedation in the Emergency Department but has not yet been standardized as an induction agent. We are obtaining funding for a pilot study to validate the use of ketofol as an induction agent.

Eligibility

Minimum Age Eligible for Study:	18 Years
Maximum Age Eligible for Study:	60 Years
Genders Eligible for Study:	Both

Criteria

Inclusion Criteria: - American Society of Anesthesiologists (ASA) physical status I and II who are to undergo elective general, urologic, orthopedic, plastic, or gynecologic surgery. Exclusion Criteria: - patients with age less than 18 yr or over 60 yr, - emergency surgery, - patients undergoing neurosurgical procedures, - any procedure with adjunctive analgesia, - any patient on chronic opiate use, - females who

are known to be pregnant, - patients who had ingested psychotropic or sedative medication within one month of investigation, - patients with personality disorders, - weight greater than 20% of ideal, and - any known contraindications to ketamine or propofol.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01065350

Locations

Dartmouth Hitchcock Medical Center

Facility:	Lebanon, New Hampshire, 03756, United States

Sponsors and Collaborators

Mayo Clinic

More Information

Other Publications

First Received:	February 7, 2010
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Health Authority:	United States: Institutional Review Board

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