Effect of Remifentanil on Electroencephalographic BAR Index During Propofol Anaesthesia

This study is currently recruiting patients.
Verified by Melbourne Health March 2007

Sponsors and Collaborators:	**Melbourne Health** Biopharmica Limited
Information provided by:	Melbourne Health
ClinicalTrials.gov Identifier:	NCT00455026

Purpose

Current cortical EEG based depth of anaesthesia monitors do not accurately reflect the effect of opioid drugs. We have developed a new theoretically-based method of analysing the EEG. Our hypothesis is that this new method will more accurately predict depth of anaesthesia than the Bispectral Index (BIS) monitor in patients having elective surgery.

Condition	Intervention	Phase
Depth of Anaesthesia	Drug: remifentanil	Phase I

MedlinePlus consumer health information

Study Type: Interventional
Study Design: Diagnostic, Randomized, Double-Blind, Dose Comparison, Parallel Assignment, Pharmacodynamics Study

Further study details as provided by Melbourne Health:
Primary Outcome Measures:

- Prediction probability for prediction of anaesthetic endpoints

Total Enrollment: 45

Study start: March 2006

Patients aged 18-60 years presenting for elective surgery under general anaesthesia will be recruited. They will be randomised to receive remifentanil effect-site target 0, 2 or 4 ng/ml. Then anaesthesia will be induced with propofol. Loss of the eyelash reflex, response to command and response to electrical stimulation will be measured. The raw EEG will be recorded and analysed off-line using our new method and also for BIS values. Anaesthesia will then proceed according to the needs of the patient and the surgery.

Eligibility

Ages Eligible for Study: 18 Years - 60 Years, Genders Eligible for Study: Both
Criteria

Inclusion Criteria:

- Male and female patients, aged 18-60 years, of ASA physical status 1-3, presenting for elective surgery under general anaesthesia

Exclusion Criteria:

- Inadequate English comprehension due to a language barrier, cognitive deficit or intellectual disability
- Epilepsy or other EEG abnormality
- Prescription or illicit drugs known to affect the EEG

Location and Contact Information

Please refer to this study by ClinicalTrials.gov identifier NCT00455026

Kate Leslie, MD 61-3-93427000 Ext. 27540 mailto:kate.leslie@mh.org.au?subject=NCT00455026, 2005.236: - Effect of Remifentanil on Electroencephalographic BAR Index During Propofol Anaesthesia

Australia, Victoria
Royal Melbourne Hospital, Parkville, Victoria, 3050, Australia; Recruiting
Kate Leslie, MD 61-3-93427000 Ext. 27540 mailto:kate.leslie@mh.org.au?subject=NCT00455026, 2005.236: - Effect of Remifentanil on Electroencephalographic BAR Index During Propofol Anaesthesia
Kate Leslie, MD, Principal Investigator

Swinburne University, Hawthorn, Victoria, 3123, Australia; Not yet recruiting
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David Lilley, PhD, Principal Investigator

Study chairs or principal investigators

Kate Leslie, MD, Principal Investigator, Melbourne Health

More Information

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Health Authority: Australia: Department of Health and Ageing Therapeutic Goods Administration
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