ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Trial record **1 of 1** for: nct01920113

Previous Study | Return to List | Next Study

A Comparison of Efficacy and Safety During Endoscopic Submucosal Dissection Between Dexmedetomidine-remifentanil and Propofol-remifentanil

This study is ongoing, but not recruiting participants.

Sponsor:
Yonsei University

Information provided by (Responsible Party):
Yonsei University

ClinicalTrials.gov Identifier:
NCT01920113

First received: July 23, 2013
Last updated: August 6, 2013
Last verified: August 2013
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

Adequate, safe sedation is essential for Endoscopic submucosal dissection. Dexmedetomidine is a potent and selective a2-adrenoceptor agonist used for sedative and analgesic effects, but it is limited to use alone. The investigators designed this study to compare the effect and safety of two sedatives, dexmedetomidine and propofol in Endoscopic Submucosal Dissection (ESD), when sufficient analgesia-remifentanil is administered all throughout the procedure.

Condition	Intervention
Early Gastric Cancer Patients Who Were Scheduled for Endoscopic Submucosal Dissection	Drug: Dexmedetomidine - remifentanil group Drug: Propofol - remifentanil group

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Single Blind (Subject)
Primary Purpose: Treatment

Resource links provided by NLM:

MedlinePlus related topics: Endoscopy

Drug Information available for: Propofol Dexmedetomidine Remifentanil hydrochloride Dexmedetomidine hydrochloride

Genetic and Rare Diseases Information Center resources: Stomach Carcinoma

U.S. FDA Resources

Further study details as provided by Yonsei University:

Primary Outcome Measures:

- A comparison of safety during endoscopic submucosal dissection between dexmedetomidine-remifentanil and propofol-remifentanil
  [Time Frame: right after the drugs had administered] [Designated as safety issue: No]

  Safety : whether the complications as follows occur or not

  a. systolic blood pressure under 90mmHg or 20% out of range of the baseline SBP
  b. heart rate under 50bpm
  c. oxygen saturation under 90%, respiratory rate under 7 per minute

Secondary Outcome Measures:

- A comparison of efficacy during endoscopic submucosal dissection between dexmedetomidine-remifentanil and propofol-remifentanil
  [Time Frame: right after the drugs had administered] [Designated as safety issue: No]

  Efficacy :

a. whether a bolus injection of 10 mg of propofol was administered or not
b. evaluating the depth of sedation using MOAA/S scale all through the procedure
c. whether the en bloc resection, complete resection were done or not under the sedation

Other Outcome Measures:

- A comparison of patient's satisfaction during endoscopic submucosal dissection between dexmedetomidine-remifentanil and propofol-remifentanil [Time Frame: within 24hrs after procedure] [Designated as safety issue: No]

  Patients' satisfaction : investigate in four steps questionaire (very good, good, bearable and unbearable) when the patients' were discharged from PACU

- A comparison of gastric motility, easiness for procedure, operator's satisfaction during endoscopic submucosal dissection between dexmedetomidine-remifentanil and propofol-remifentanil [Time Frame: right after the drugs had administered]
  [Designated as safety issue: No]

  Subjects' motility grading during procedure, easiness of procedure, operator's satisfaction : investigate in four steps questionaires by the operator after the procedure

Enrollment:	60
Study Start Date:	October 2012
Estimated Study Completion Date:	September 2013
Primary Completion Date:	December 2012 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: DR group In Group DR, a bolus dose of 0.5mcg/kg dexmedetomidine was injected intravenously 5 minutes before the start of the procedure (Precedex®, Abbott, Istanbul, Turkey). And a continuous infusion dose of 0.3-0.7mcg/hr/kg was started.	Drug: Dexmedetomidine - remifentanil group
Active Comparator: PR group In Group PR, a bolus injection of 1 mg/kg of propofol was followed by a continuous infusion at a rate of 3-5mg/hr/kg(Pofol®, Dongkook Pharm. Co. Ltd., Seoul, Korea) using an infusion pump (Syringe Pump TE-331, Terumo Japan).	Drug: Propofol - remifentanil group

Eligibility

Ages Eligible for Study:	20 Years to 90 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Age ≥20
- American Society of Anaesthesiologists(ASA) physical status classification I~III
- Early gastric cancer patients who were scheduled for Endoscopic submucosal dissection

Exclusion Criteria:

- Age < 20
- American Society of Anaesthesiologists(ASA) physical status classification IV
- those with end-organ diseases (i.e. heart failure, respiratory failure, hepatic failure, renal failure)
- known drug allergies or history of drug abuse
- psychological disease

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01920113

Locations

Korea, Republic of

Anesthesiology & Pain Medicine, Yonsei university college of medicine
Seoul, Korea, Republic of, 120-752

Sponsors and Collaborators

Yonsei University

More Information

No publications provided

Responsible Party:	Yonsei University
ClinicalTrials.gov Identifier:	NCT01920113 History of Changes
Other Study ID Numbers:	4-2012-0621
Study First Received:	July 23, 2013
Last Updated:	August 6, 2013
Health Authority:	South Korea: Korea Food and Drug Administration (KFDA)

Keywords provided by Yonsei University:

Endoscopic submucosal dissection	dexmedetomidine
propofol	efficacy
remifentanil	safeness

Additional relevant MeSH terms:

Stomach Neoplasms	Analgesics
Digestive System Diseases	Analgesics, Non-Narcotic
Digestive System Neoplasms	Analgesics, Opioid
Gastrointestinal Diseases	Anesthetics
Gastrointestinal Neoplasms	Anesthetics, General
Neoplasms	Anesthetics, Intravenous
Neoplasms by Site	Central Nervous System Agents
Stomach Diseases	Central Nervous System Depressants
Dexmedetomidine	Hypnotics and Sedatives
Propofol	Molecular Mechanisms of Pharmacological Action
Remifentanil	Narcotics
Adrenergic Agents	Neurotransmitter Agents
Adrenergic Agonists	Peripheral Nervous System Agents
Adrenergic alpha-2 Receptor Agonists	Pharmacologic Actions
Adrenergic alpha-Agonists	Physiological Effects of Drugs

ClinicalTrials.gov processed this record on November 16, 2014