Official Title： Triple Combination of Fosaprepitant, Dexamethasone and Palonosetron Versus Combination of Dexamethasone and Palonosetron for the Prevention of Postoperative Nausea and Vomiting in Patients Undergoing Laparoscopic Gastrointestinal Surgery

NCT number： NCT04853147

Date of the document： 18/04/2021

This study is a single-center, randomised, controlled, double-blind, parallel-group clinical trial

Study design

Patients is randomized in a 1:1 ratio to receive either triple therapy or doublet therapy using computer-generated codes with randomly block sizes. Randomization is stratified based on the apfel score (3 or 4). Triple therapy is combined with fosaprepitant plus dexamethesone and palonosetron. doublet therapy is combined with placebo (normal saline) plus dexamethesone and palonosteron. The study drug is prepared by the nurses in anesthetic pharmacy who do not participate in this trail. Allocation is concealed from the investigators, patients and surgeons. Fosaprepitant and placebo were contained in identical intravenous infusion bags. Study drug or placebo infusion was initiated before anesthetic induction. Dexamethasone and palonosetron are injected at induction in both group.

Anaesthetic protocol

A standardized total intravenous anaesthetic protocol will be applied to all patients. General anaesthesia will be induced with intravenous administration of propofol, cisatracurium and remifentanil. The anesthesia will be maintained by propofol and remifentanil under monitoring of the bispectral index. Standard patient monitoring including ECG, pulse oximetry, capnography, blood pressure will be performed. Before skin incision, non-steroidal anti-inflammatory drug (NSAID) will be injected for preemptive analgesia. At the end of surgery, ropivacaine was used as local infiltration anesthesia around the wound and intravenous patient-controlled analgesia containing hydromorphone and NSAID will be connected to patients at the end of surgery.

Statistical analysis

The hypothesis of this study is that the proportion of participants with PONV for triple therapy will be significantly lower than that for doublet therapy. A sample size of 1154 patients will be selected on the basis of the following assumptions: (1) the proportion of participants with PONV is about 50% in doublet therapy and is

estimated to 40% in triple therapy, (2) α =0.05, (3) power 90% and (4) missed follow-up rate 10%.

Subgroup analysis will be stratified by apfel score, surgical site, or age respectively.