

Scott & White Hospital & Clinics Clinical Research at Scott & White

Please complete this form for each of your studies that are currently enrolling subjects. This information will be used to create a web page available for viewing by the general public. Please use lay terminology as in the consent form. The information should be complete and accurately describe your studies.

Study Title: A Double-Blind, Multi-Center, Randomized, Stratified, Parallel, 2 Arm, Phase 2 Study to Assess Palonosetron vs. Ondansetron as Rescue in Subjects that Developed Postoperative Nausea and Vomiting (PONV) in the Postanesthesia Care Unit (PACU)

Project ID#: 81620

Department: Anesthesia

Sponsor: Helsinn Healthcare SA

Study Managed By: Eisai, Inc.

1. Provide a brief synopsis of the study (purpose of the study from abstract, consent form, or protocol using lay terminology):

Condition(s):	Treatment(s):
Post operative nausea and vomiting (PONV)	palonosetron IV (0.075 mg) and ondansetron IV (4mg)

Post operative nausea and vomiting (PONV) is a frequent complication following anesthesia and surgery. It is associated with considerable medical and economic impact and high levels of patient discomfort and dissatisfaction. There are several medications, called antiemetics, which are currently available to prevent PONV and are typically given to patients prior to anesthesia and surgery. Palonosetron and ondansetron are both antiemetic medications approved by the U.S Food and Drug Administration (FDA) for preventing PONV. To date, few studies have been conducted to determine the benefits, if any, to administering these drugs as rescue medication to treat patients who develop PONV while recovering from their surgery in the post anesthesia care unit (PACU). The purpose of this study is to determine if a single dose of palonosetron is more effective than ondansetron when given as rescue medication to treat PONV in the PACU.

You have been asked to participate in this research study because you have a high risk for developing PONV and you have been scheduled for elective laparoscopic surgery (a minimally invasive surgical procedure involving the abdomen or pelvic region of the body).

2. Who is eligible to participate in the study (basic qualifications such as age, gender, etc.)?

Age: 18 years or older

Gender: Male or Female

- You have the presence of at least 2 of the following PONV risk factors:
 - 1). You are female
 - 2). You must have a history of PONV and/or are prone to motion sickness
 - 3). You must have a non-smoking status (or quit smoking 12 months ago)
- You must be having elective laparoscopic abdominal or gynecological surgery

Patients **cannot** participate in this study if the following apply:

- You are a female of child-bearing potential and are unwilling to use medically accepted methods of birth control throughout the study; you are pregnant or breastfeeding.
 - You are morbidly obese, defined as a body mass index (BMI) greater than 40 or more than 100 lbs over your ideal body weight
 - You are a cancer patient and you have received chemotherapy within 4 weeks prior to study entry
 - You suffer from epilepsy (uncontrolled seizures or body movements)
 - You have taken any antiemetic drug (prevents nausea and vomiting) within 24 hours prior to your elective surgery
 - You experience nausea or vomiting 24 hours prior to your elective surgery
 - You have a history of alcohol and illegal drug abuse.
 - You have a known allergy to the study drugs.
 - You have participated in a clinical study involving another investigational drug or device within 30 days prior to study entry.
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3. What may be involved/required for subject participation (visits, tests, and/or logs, etc.)?

If you agree to take part in this study, your participation will last for approximately 5 days. This study includes a screening visit, a treatment visit (the day of your scheduled surgery), and a follow-up telephone call on day 4 or day 5. You will also be asked to complete a diary each day for 3 days following your surgery. This diary will require you to record any symptoms of nausea, vomiting, retching, and pain.

Screening Visit

If you choose to take part in this research study, a screening visit will be scheduled within 2 weeks of your planned surgery in order to determine if you qualify for the study. During this office visit, the study doctor will perform the following tests and procedures:

- A routine physical examination - including vitals and demographic information (blood pressure, heart rate, weight, height, etc.)
- Review medical history and medications you are currently taking
- Pregnancy test

If you qualify based on the results of these screening procedures, the study staff will give you instructions on how to complete the subject diary and enroll you into the study.

Treatment Visit

If you experience nausea or vomiting, while you are recovering in the PACU, within 6 hours after your surgery, you will be asked to rate your level of PONV (i.e., low, high) and you will be randomly assigned (like the flip of a coin) to one of the two treatment groups:

- palonosetron IV (0.075 mg)
- ondansetron IV (4 mg)

Both groups will be given a single dose of study drug (palonosetron or ondansetron) intravenously (IV - into a vein). The study drug will be supplied by Eisai, Inc. (Study Management Company from Helsinn Healthcare SA; the Sponsor).

You will not know which treatment group you have been assigned to until your participation in the study is complete.

At hospital discharge, you will be given a diary to record your symptoms and a pre-addressed, pre-paid envelope to mail your completed diary back to the study site following the telephone contact (discussed below).

Telephone Contact

On Day 4 or 5 following your surgical procedure, study staff will contact you by telephone. You will be asked questions about your general health, any nausea/vomiting you have experienced, any medications you may have taken, and whether you have experienced any side effects.

4. Contact Information:

Coordinator(s): Tiffany Mendoza, RN

Title(s): Clinical Research Coordinator

Telephone Number(s) (no pager numbers): 254-724-5566

E-mail Address(es): tmendoza@swmail.sw.org
