Effects of ondansetron dose and timing
on rates of post-operative nausea and vomiting
PI: Dr. Daniel Katz
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Mount Sinai

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Mount Sinai Brooklyn
The Mount Sinai Hospital
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Initial Application
IRB-17-02095
Daniel Katz

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1. Summary - Title

Protocol Title

Effects of ondansetron dose and timing
on rates of post-operative nausea and vomiting

Principal Investigator Daniel Katz

When the application is complete, it will be sent to the PI for submission

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Primary Department Anesthesiology

When the application is complete, it will be sent to the PI for submission

Application Initiated By David Maerz

Lay Summary

Post-operative nausea and vomiting represent a significant concern for perioperative and postoperative professionals as it can lead to increased morbidity among patients. In addition, it is being increasingly recognized as a primary source of patient discomfort and dissatisfaction, often exceeding complaints regarding pain. This has led to its adoption into a number of currently existing quality measures.

Several medications and strategies currently exist with the aim of reducing the overall incidence of post-operative nausea and vomiting. We seek to compare three different regimens of the often used medication ondansetron in order to determine if there is a difference between these regimens and if an optimal one exists. We are using standard doses of ondansetron for this study and wish to examine the function of time as an additional component of the dosing. Prior studies have established the principals we are using, but none have taken the final task of comparing these regimens.

IF Number IF2092854

2. Summary - Setup

Funding Has Been Requested / Obtained	No
Application Type	Request to Rely on Mount Sinai IRB
Research Involves	Prospective Study ONLY
Consenting Participants	Yes
Requesting Waiver or Alteration of Informed Consent for Any Procedures	No
Humanitarian Use Device (HUD) Used Exclusively in the Course of Medical Practice	No
Use of an Investigational Device to Evaluate Its Safety or Effectiveness	No
Banking Specimens for Future Research	No
Cancer Related Research that Requires Approval from the Protocol Review and Monitoring Committee (PRMC).	No

Is this Cancer Related Research? Cancer Related Research is defined as research that has cancer endpoints or has a cancer population as part of or all of its targeted population. This includes protocols studying patients with cancer or those at risk for cancer.

Clinical Trial	Yes

**** A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).***
**** Used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective.***

Drugs / Biologics	No

**** Drugs / Biologics That Are Not a Part of Standard Practice***
**** Controlled Substances***
**** Drugs / Biologics Supplied by the Research Sponsor or Purchased with Study Funds***

Ionizing Radiation for imaging or therapy, including X-Ray, Fluoroscopy, CT, Nuclear Medicine, PET andor Radiation Therapy:

*** Purely for standard of care:**	No
*** In frequency or intensity that exceeds what is necessary for standard of care:**	No

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Hazardous Materials	No

**** Recombinant DNA***
**** Viral Vectors***

**** Plasmids***
**** Bacterial Artificial Chromosomes***
**** Toxic Chemicals, Potentially Toxic Medications, Carcinogens***
**** Autologous Cell Lines***

Request Use of Clinical Research Unit Resources No

3. Summary - Background

Objectives

Determination of whether differing standard dosing regimens of ondansetron produce different levels of effect in regards to the incidence of early and late post-operative nausea and vomiting.

Background

Post-operative nausea and vomiting (PONV) is a significant concern in all patients undergoing any form of anesthesia with a varied level of incidence from 20% to as high as 80% in some studies [1]. PONV is a significant cause of morbidity and dissatisfaction among patients, and begins to become a systems concern when it takes place in the ambulatory surgery environment. The Previous studies have indicated a high prevalence of ambulatory surgery in the United States, representing up to and in some studies exceeding 60% of all surgical procedures [1]. Post-operative nausea and vomiting represents a significant cause of unanticipated requirement for hospital admission following ambulatory surgery, representing 7.4% of unanticipated admissions in one study [2]. Examination of potential costs relating to PONV demonstrated less spent on patients who received perioperative anti-emetics vs. those who did not receive prophylaxis (considering drug costs) [1].

Ondansetron has been well established medication for the prophylaxis of PONV for well over a decade across several patient populations [3,4]. Several studies have been performed to determine the difference between dose levels and regimens of ondansetron with varied results. However, certain consensuses seem to exist among studies with a dose of 4mg Ondansetron given nearing the end of the procedure before anesthesia finish time having a greater effect on PONV prophylaxis than a single dose given before or at the procedure start time [5,6,7]. A previous study conducted to compare a dose of 4mg Ondansetron at the beginning of the surgical case, compared to 4mg Ondansetron approaching surgical finish, to a divided dosing of 2mg Ondansetron in the beginning and 2mg Ondansetron at the end demonstrated that 4mg at the end was superior to the divided 2mg + 2mg dosing which was superior to the 4mg at the beginning [7]. Some studies have compared 8mg of Ondansetron at the end of surgery to 4mg Ondansetron with varying results, some showing it as more effective and others failing to distribute a consistent improvement, no studies reported an increased incidence of side effects [8,9].

References

1. Hill R., et al. Cost-effectiveness of Prophylactic Antiemetic Therapy with Ondansetron, Droperidol, or Placebo. Anesthesiology. 2000;92:958-67.
2. Linares-Gil, et al. Unanticipated admissions following ambulatory surgery. Ambulatory Surgery. 1989;5:183-8.
3. Gupta P, Jain S. Postoperative nausea and vomiting prophylaxis: a comparative study of ondansetron, granisetron, and granisetron and dexamethasone combination after modified radical mastectomy. Saudi Journal of Anaesthesia. 2014;8:S67-71.
4. Ummenhofer W, et al. Effects of ondansetron in the prevention of postoperative nausea and vomiting in children. Anesthesiology. 1994;81:804-10.
5. Cruz N, Portilla P, Vela R. Timing of ondansetron administration to prevent postoperative nausea and vomiting. P R Health Science Journal. 2008;27:43-7.
6. Sun R, Klein K, White P. The Effect of Timing of Ondansetron Administration in Outpatients Undergoing Otolaryngologic Surgery. Anesthesia & Analgesia. 1997;84:331-6.
7. Tang J, et al. The Effect of Timing of Ondansetron Administration on its Efficacy, Cost-Effectiveness, and Cost-Benefit as a Prophylactic Antiemetic in the Ambulatory Setting. Anesthesia & Analgesia. 1998;86:274-282.
8. Paventi S, Santevecchi A, Ranieri R. Efficacy of a single-dose ondansetron for preventing post-operative nausea and vomiting after laparoscopoic cholecystectomy with sevoflurane and remifentanil infusion anaesthesia. Eur Rev Med Pharmacol Sci. 2001;5:59-63.
9. Honkavaara P. Effect of ondansetron on nausea and vomiting after middle ear surgery during general anaesthesia. British Journal of Anaesthesia. 1995;76:316-18.

Primary and Secondary Study Endpoints

Primary Endpoint: Cumulative incidence of reported post-operative nausea and vomiting

Secondary Endpoints: Early post-operative nausea (0-6 hours post-operative), early post-operative vomiting (0-6 hours post-operative), late post-operative nausea (6-48 hours post-operative), late post-operative vomiting (6-48 hours post-operative), type of surgery, duration of surgery, duration of anesthesia care, need for dosing of anti-emetics following end of anesthesia time, need for "rescue" anti-emetics during anesthesia time

Protocol Was Already Approved by the Icahn School of Medicine at Mount Sinai (ISMMS) Institutional Review Board (IRB) Under a Different Principal Investigator	No
Protocol Was Previously Submitted to an External(non-ISMMS) IRB	No

4. Research Personnel

Name/Department	Role/Status	Contact	Access	Signature Authority	Phone	Email
Daniel Katz / Anesthesiology	PI / Faculty		SIGNAUTH			
David Maerz / Anesthesiology	Co-Investigator /		EDIT			
Chang Park / Anesthesiology	Co-Investigator /		EDIT		6464135254	
Monique Pierre / Anesthesiology	Admin (non-FCOI) / Staff (non MD)		EDIT		212-241-7749	
John Martins / Anesthesiology	Co-Investigator /		READONLY			
Dennis Wolf / Anesthesiology	Co-Investigator /		READONLY			

5. Sites

Site Name	Icahn School of Medicine at Mount Sinai
Other External Site Name	
Contact Details	
Approved	
Approval Document	
Funded By Mount Sinai	
Other IRB	

6. Subjects - Enrollment

Site Name	Icahn School of Medicine at Mount Sinai
Subjects To Be Enrolled	
300	
Total Number of Subjects to be Enrolled Across All Listed Sites Above (Auto Populated)	300

7. Subjects - Setting and Resources

Setting of Human Research Other

Specify Other Setting of Human Research

5 East 98th St Ambulatory Surgery Center

Total Number of Subjects Needed To Complete Study 300

Feasibility of Meeting Recruitment Goals

Familiarity and experience working at the 5 East 98th st practice has yielded that at least 3-5 cases are done there on a daily basis making the recruitment goals feasible to meet within a period as short as 3-6 months.

Facilities To Be Used for Conducting Research

The operating rooms where the 5 East 98th st ambulatory surgery cases will be performed.

Multi-Center Study No

Community-Based Participant Research Study No

PI must attest to the following.

**** Process is adequately described to ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.***

8. Subjects - Populations

Inclusion Criteria

Any patient undergoing an ambulatory surgery case at 5 East 98th st regardless of level of anesthesia planned for administration (mild sedation to general anesthesia).

Exclusion Criteria

Allergy or prior intolerance to dexamethasone, allergy or prior history of intolerance to ondansetron, concomitant use of apomorphine, and pregnant patients. In addition any patient with an officially diagnosed Long-QT syndrome. Patients currently on pre-operative steroids will also be excluded.

Enrollment Restrictions Based Upon Gender, Pregnancy, Childbearing Potential, or Race	Yes

Justify Restriction(s)

Ondansetron does not have FDA approval for use as an anti-emetic in pregnant patients.

Age Range(s)	18 to 64 Years, 65 Years and Over
Targeted Population(s)	Adults - Patients

Other Aspects that Could Increase Subjects Vulnerability

The main aspect that could increase subject's vulnerability is anxiety on the day of the procedure.

Safeguards to protect Subjects rights and welfare

Subjects will be assured that their decision to participate or decline to participate in the study will in no way affect the kind of anesthetic or surgical care that they receive. In addition, they will be assured that all arms of the study are aimed at prevention of post-operative nausea and vomiting, are each used by practitioners within the institution, and each represents modalities with aspects shown to be successful in attempts at post-operative nausea and vomiting prevention.

9. Subjects - Participation

Duration of an Individual Subjects Participation in the Study

Day of surgery to end of 48 hour post-operative period.

Duration Anticipated to Enroll All Study Subjects

All subjects are expected to be enrolled within a 9 month period.

Estimated Date for the Investigators to Complete This Study Within one year

Procedures for Subjects to Request Withdrawal

Subjects may withdraw from the study at any point leading up to initiation of surgical start time. Following the end of anesthetic care they may request to withdraw from the study which would result in their episodes of post-operative nausea and vomiting to not be recorded as data and for any data sheets relevant to them to be destroyed. They would still receive a standard post-operative phone call, but the nurses will be instructed to not explicitly record their responses on a study sheet.

Procedures for Investigator to Withdraw Subjects

Investigators will withdraw subjects from the study if they are not able to receive the dictated medication dose (such as drug not available or practitioner neglected to administer) at which point their data sheet will be destroyed and disposed of in a secure patient confidential disposal bin present at the site.

Participants Will Be Recruited Yes

Recruitment Method(s) Clinical Practice

How Participants Will Be Identified

Any patient undergoing a procedure at the 5 East 98th Street ambulatory surgical practice location who does not possess one of the exclusion criteria. The clinical anesthesiology team will do their initial assessment and screen for potential subjects. Once identified, the research team will then approach the patients.

Who Will Initially Approach Potential Participants Treating Physician

How Research Will Be Introduced to Participants

Following the patient being consented and pre-operaticely examined by the Anesthesiologist and Surgeon as part of standard procedure, they will be re-approached by the Anesthesiologist and have the study described to them and given the opportunity to consent.

Given that this surgical center performs cases for many many surgeons there is no way to inform subjects about the study prior to the day of the surgery. We have therefore designed an information sheet describing the study that will be sent to the surgeons for distribution to their patients.

How Participants Will Be Screened

Screening will be part of the pre-operative examination which should identify any of the exclusion criteria.

10. Subjects - Risk and Benefits

Risks to Subjects

The primary salient risk to subjects due to this study is the added anxiety on the day of their procedure. Other risks are those associated with the two study drugs dexamethasone and ondansetron. There is a risk of temporary headache associated with ondansetron usage that varies in studies from 0.1-9%. However, the doses of ondansetron being used are less than that described in the package insert in regards to side effects (12-16mg in package insert compared to 4-8mg in study).

Side effects of Dexamethasone when given as a one time dose of 4mg are very mild and transient. A small subset of patients may see a small rise in serum glucose concentration, however this has been shown in multiple studies to not be clinically significant, even in patients with diabetes. Although with higher and repeated doses of steroids there is also a risk of infection, a single small dose of dexamethasone does not increase the risk of an infectionas demonstrated in several studies. There is also a risk of allergy to any medication, however, steroids are often used to treat allergy and as such this risk is very low.

In addition, there is a risk of being involved in a study as it has the chance to provide a distraction to the individual administering medications as it may deviate from his/her typical behavior.

However, the drug risks are not significantly increased as a result of this study as they are typically administered to all patients undergoing anesthetic care at Mount Sinai Hospital. The advent of CMS Merit Based Incentives Payments (MIPS) adoption by the hospital has resulted in >75% of patients already receiving this combination per standard care.

There is also the risk of loss of confidentiality.

Description of Procedures Taken to Lessen the Probability or Magnitude of Risks

In order to lessen the magnitudes of risks we have designed a pragmatic protocol that mirrors the common behaviors in the department in terms of dosing time which also closely mirrors the literature. This should lessen any behavioral interference of the study.

In terms of drug side effects, we are using a drug that is typically used for PONV prophylaxis and is used extensively within the department. Adding on to this we are using ondansetron dosing regimens that are well below the limits in the package insert and those associated with the side-effect of headache.

In order to reduce stress to the participant, the individual consenting will emphasize no impact will occur relating to surgical or anesthetic care as a result of declining to participate, and that the study involves practices commonly used in the department.

Provisions for Research Related Harm / Injury

Patients will have availability of care within the Mount Sinai Hospital relating to any anxiety or drug based harms that could occur. Beyond this the study does not present more than minimal risk.

Expected Direct Benefit to Subjects

The expected direct benefit is a reduced incidence of post-operative nausea and vomiting. All three arms of the study have been proven to be effective in reducing PONV and none of the three has been studied directly yet to prove definitive superiority to any of the other treatments used in this study.

Benefit to Society

PONV represents a common reason for admission following ambulatory surgery, this reduction of PONV can result in less costs incurred by the hospital, insurance companies, and tax payers.

Provisions to Protect the Privacy Interests of Subjects

The subjects will only interact with members of their care team that they would have interacted with if this study did not exist. Their consent will be from their primary Anesthesiologist doing the case and their post-operative follow up once they go home will be done by the 5E98th street nurse who normally would be calling for follow up. This will prevent any additional impact on the patients relating to additional care team members.

There are no plans for additional follow up beyond the normal post-operative period.

Economic Impact on Subjects

No economic cost is anticipated for subjects as this will not affect their anesthetic service billing. There is a possible economic benefit if they are able to avoid an unexpected hospital admission due to prevention of their PONV.

11. Procedures - Narrative

Description of the Study Design

Randomized controlled clinical trial.

Patients will be consented at the time of their anesthesia consent on the day of their procedure. If the patient consents they will be randomized to one of the three arms of the study, if they refuse they will receive standard pre, peri, and post-operative care.

The first treatment arm consists of 4mg Dexamethasone given between anesthesia induction and procedure start time and a dose of 4mg Ondansetron given before procedure finish time with the aim of it being 30 minutes prior to anticipated procedure finish.

The second arm consists of 4mg Dexamethasone given between anesthesia induction and procedure start time along with a dose of 4mg Ondansetron given at the same time followed by an additional dose of 4mg Ondansetron given before procedure finish time with the aim of it being 30 minutes prior to anticipated procedure finish.

The third arm consists of 4mg Dexamethasone given between anesthesia induction and procedure start time and a dose of 8mg Ondansetron given before procedure finish time with the aim of it being 30 minutes prior to anticipated procedure finish.

The data recorded with be the patient's age and sex, the type of procedure performed, the duration of the procedure, the duration of anesthesia, the time of antiemetic dosing, and the dose of antiemetic given.

Following the anesthesia finish, the patient will be monitored in the recovery area per normal protocol and the patient's nurse will be instructed to record any incidents of vomiting and the patient will be queried regarding their nausea immediately upon arrival into the recovery area, one hour following arrival, and immediately prior to discharge. All responses will be recorded.

Patients will then be contacted the next day per normal protocol, with the addition that the nurse will specifically ask about any episodes of nausea and vomiting in this period and will record them accordingly.

Description of Procedures Being Performed

A dose of dexamethasone will be administered at the time of induction of anesthesia and before procedure start time. Depending on which arm the patient is randomized to they will either receive a dose of ondansetron at this time or will solely receive a dose of ondansetron before procedure finish. This will involve the injection of an IV medication through an already existing intravenous line.

A data sheet will then be filled out post-operatively describing any episodes of nausea or vomiting as well as any additional anti-emetics given. The patients will be called as part of normal post-operative care and any episodes of nausea and vomiting disclosed will be recorded on the sheet.

Description of the Source Records that Will Be Used to Collect Data About Subjects

Source records will be the data sheet filled out during the time the patient is at 5 East 98th sheet and during their post-operative call.

Description of Data that Will Be Collected Including Long-Term Follow-Up

Data collected will be: the patient's age and sex, the type of procedure performed, the duration of the surgery, the duration of the anesthesia care, the anti-emetics administered perioperatively and postoperatively, any recorded episodes of nausea and vomiting in the post-operative period at 5 East 98th and upon the post-operative phone call.

No follow up beyond the post-operative phone call period is planned.

Research Requires HIV Testing No

12. Procedures - Genetic Testing

Genetic Testing Will Be Performed No

Guidance and Policies > Future Use Data Sharing and Genetic Research

13. Procedures - Details

Surveys or Interviews	No
Audio / Photo / Video Recording	No
Deception	No
Results of the Study Will Be Shared with Subjects or Others	No

14. Procedures - Compensation

Compensation for Participation No

15. Consent - Obtaining Consent

Consent Process Adult Consent

Where and When Consent Will Be Obtained

5 East 98th street ambulatory surgery practice

Waiting Period for Obtaining Consent

Waiting period will be the time between the study being described and prior to the patient being escorted for surgery. This typically is around 30 minutes but can vary to as long as 60 minutes.

SOP HRP-090 Informed Consent Process for Research Is Being Used Yes

PPHS Worksheets, Checklists and SOPs

Process to Document Consent in Writing Will Use Standard Template

Non-English Speaking Participants Will Be Enrolled Yes

What Languages Other Than English Will Be Used

Spanish

What Process Will Be Used Long Form

The consent document must be translated into the language of the potential subject, and approved by the IRB, before you can go through the consent process with the non-English speaking person. If, after the project is approved, a short form consent process is needed, please see the PPHS policy and submit a modification.

16. Consent - Documents

Consent Documents

Type	Oral Consent Script
Name	Oral Consent Script
Upload	PONV Oral Consent Script.docx
Type	Waiver Checklist
Name	Waiver Checklist
Upload	PONV HRP-416 - CHECKLIST - Waiver of Written Documentation of the Consent Process.docx

Consent Templates

17. Data - Collection

Health Related Information Will Be Viewed, Recorded, or Generated Yes

Description of Health Information That Will Be Viewed, Recorded, or Generated

Past medical history, surgical procedure, allergies, duration of surgery, duration of anesthesia, medications administered during visit, and results of post-operative contact.

Non-Health Related Information Will Be Viewed or Recorded Yes

Description of Non-Health Information That Will Be Viewed or Recorded

Patient's sex and age.

HIV / AIDS Related Information Will Be Viewed or Recorded No

Data That Will Be Viewed, Recorded, or Generated Contains ANY of the Following Directly Identifiable Information No

**** Name***
**** Social Security Number***
**** Medical Record Number***
**** Address by Street Location***
**** Telephone Number***
**** Fax Number***
**** Web Uniform Resource Locators (URLs)***
**** Internet Protocol (IP) Address***
**** Health Plan Beneficiary Number***
**** Account Number***
**** Certificate***
**** License Number***
**** Vehicle Identification Number (Including License Plate Numbers)***
**** Full-Face Photographic Images***
**** Biometric Identifiers (Finger and Voice Prints)***
**** Geographical Subdivisions Smaller Than a State***
**** All Elements of Dates for Dates Directly Related to an Individual (i.e., Birth Date, Admission Date, Discharge Date)***
**** Email Address***

Data Collection Sheet

A Data Collection Sheet is required if you are either performing a retrospective review, or your study meets the category of exempt 4 research, or your study meets the category of expedited 5 research. Please upload it here.

Data Collection Source(s) Participant

18. Data - Storage

Location Where Data Will Be Stored

Data will be stored on an encrypted drive on an encrypted server on a computer within the PIs office. The binder containing date sheets will also be kept in the PIs office in a locked cabinet behind a door accessible via a T9 code.

How will the data be stored?	Anonymously
Research Personnel Responsible for:	Daniel Katz
Accessing Data	Yes
Receipt or Transmission of Data	Yes
Holding Code That Can Be Linked to Identity of Participants	Yes
Research Personnel Responsible for:	David Maerz
Accessing Data	Yes
Receipt or Transmission of Data	
Holding Code That Can Be Linked to Identity of Participants	
Research Personnel Responsible for:	Chang Park
Accessing Data	Yes
Receipt or Transmission of Data	
Holding Code That Can Be Linked to Identity of Participants	
Research Personnel Responsible for:	Monique Pierre
Accessing Data	
Receipt or Transmission of Data	
Holding Code That Can Be Linked to Identity of Participants	
Research Personnel Responsible for:	John Martins
Accessing Data	
Receipt or Transmission of Data	
Holding Code That Can Be Linked to Identity of Participants	
Research Personnel Responsible for:	Dennis Wolf
Accessing Data	
Receipt or Transmission of Data	
Holding Code That Can Be Linked to Identity of Participants	

Duration Data Will Be Stored

Data will be stored up until study completion with publication.

Steps That Will Be Taken to Secure the Data During Storage, Use, and Transmission

The binder with the data sheet will be kept in the co-investigator's office near the endoscopy suite that is kept locked at all times and can only be accessed through T-9 door code. There will be no linking information or identifiers as part of the data sheet. Once the patient consents to the study a study number will be generated on their data sheet and the sheet will be removed from their record by the post-op phone call nurse and picked up by the research team. No linking information will be present between the data sheet and the patient.

Transmission of communications will only occur via secure sinai email means and usage will only occur on secure Mount Sinai computers on premise.

Power Analysis/Data Analysis Plan (Including Any Statistical Procedures)

Data analysis will be performed by an in-house statisician associated with the Anesthesiology department.

19. Data - Safety Monitoring

More Than the Minimum Data Safety Monitoring Will Be Done Yes

Principal Monitor Daniel Katz

Additional Monitors

Specific Items That Will Be Monitored for Safety

The PI will review with the nursing team the post-operative assessment of the patients in the study to ensure that no harm has occurred.

Frequency of Data Review

Every month the assessments will be reviewed. The data will be analyzed when half of the patients have been recruited to see if the study is necessary to continue

Rules for Alteration of Study Design

Should encounter an increase in side effects or should we find a significant difference prior to study completion we will stop recruiting.

Selection Procedures to Minimize Toxicity

There are no such procedures for this medication. It is and has been well tolerated at these doses for many many years.

Grading System to Evaluate Adverse Events

We will use a system of yes/no for adverse events.
Any event that gets a yes will then be graded on a likert scale of 1-5, 1 is minor and 5 is major.

Procedures to Assure Data Accuracy

All charts will be reviewed by the PI at the time of completion but before full anonymization to ensure data accuracy.

Suspension Reported to

the IRB

Anticipated Circumstances of Subject Withdrawal

None, this medication has been used for a long time at the doses we are administering it. We do not anticipate any issues with withdrawal of patients.

Primary or Secondary Safety Endpoints

Primary safety endpoint: general recovery profile of the patient as recorded by the nurses post operative assessment

Secondary safety endpoint: refractory nausea and vomiting

Data Monitoring Committee Description DMC Description.docx

DMC Charter Available No

Will the Research Include Data Coordinating Center Activities? No

20. Financial Administration

This information will help the Financial Administration of Clinical Trials Services (FACTS) office determine whether a Medicare Coverage Analysis (MCA) is needed for the research study. If you have any questions while completing this form, please contact the FACTS office at (212) 731-7067 or FACTS@mssm.edu.

Clinical Research Study Category Investigator Initiated

Payment Options:
**** Option 1: No protocol-required services will be billed to patients or third-party payers. Does Not Need MCA***
**** Option 2: Protocol-required services (i.e., routine care services) will be billed to patients or third-party payers. Must Have MCA***
**** Option 3: Study is initiated and federally funded by a Government Sponsored Cooperative Group who will only pay for services that are solely conducted for research purposes and other protocol-required services (i.e., routine care services) will be billed to patients or third-party payers. Billing Grid Only Required, NO MCA***
**** Option 4: Study involves only data collection and has no protocol-required clinical services. Does Not Need MCA***
**** Option 5: Study is not described in any of the above options. Please describe the study and specify whether External Sponsor (i.e., industry, government, or philanthropic source) and/or patient/third party payer will pay for protocol required services. MCA MAY Be Required***

Payment Option Option 1

No MCA is needed per option selected above.

Payment Option 1:
**** Option 1A: Department/collaborating departments will act as internal sponsor paying for all protocol-required services and no protocol-required services will be billed to patients or third party payers.***
**** Option 1B: Study involves protocol-required clinical services and an External Sponsor (i.e., industry, government, or philanthropic source) will pay for all protocol-required services.***

Payment Option 1 Option 1A

21. Attachments

Type	Name	Version	Status	Filename	Uploaded Date
Other - Other IRB Correspondance	Data Sheet	1	New	PONV Data Sheet.docx	06/29/2017
Data Monitoring Committee Description	DMC Description.docx	1	New	DMC Description.docx	08/07/2017
FDA - Package Insert for Approved Drug	Ondansetron	1	New	PackageInsertOndansetron.pdf	08/07/2017
Other - Other IRB Correspondance	IDEATE HRP-502a-MSHS TEMPLATE CONSENT DOCUMENT-ADULT 8.7.17.doc	1	New	Ideate HRP 502a-MSHS TEMPLATE CONSENT DOCUMENT-ADULT9.12.17.doc	09/12/2017
Other - Participant Educational Materials	Patient Information Sheet.docx	1	New	Patient Information Sheet.docx	08/07/2017
Consent - Consent Document	Clean Consent Version	1	New	Final Consent Clean Version 9.14.17.doc	09/14/2017