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Completed



## Netupitant and Palonosetron Hydrochloride in Preventing Chemotherapy Induced Nausea and Vomiting in Patients With Cancer Undergoing BEAM Conditioning Regimen Before Stem Cell Transplant

ClinicalTrials.gov ID  NCT03097588

Sponsor  OHSU Knight Cancer Institute

Information provided by  Joseph Bubalo, OHSU Knight Cancer Institute (Responsible Party)

Last Update Posted  2021-07-12

# Study Details Tab

### Study Overview

#### Brief Summary

This phase II trial studies how well netupitant and palonosetron hydrochloride work in preventing chemotherapy induced nausea and vomiting in patients with cancer undergoing BEAM conditioning regimen before stem cell transplant. Chemotherapy, such as carmustine, cytarabine, etoposide, and melphalan (BEAM), makes people feel sick to their stomach and causes vomiting. Netupitant and palonosetron hydrochloride may reduce the nausea and vomiting caused by the BEAM treatment.

#### Detailed Description

##### PRIMARY OBJECTIVES:

- I. To assess the efficacy of netupitant and palonosetron hydrochloride (NEPA) to prevent nausea and vomiting both during and after a highly emetogenic (BEAM) conditioning regimen for hematopoietic

stem cell transplantation (HSCT).

#### SECONDARY OBJECTIVES:

I. To differentiate response to NEPA over different phases of chemotherapy-induced nausea.

#### OUTLINE:

Within 60 minutes before standard of care BEAM treatment, patients receive netupitant and palonosetron hydrochloride orally (PO) on days 1, 3, and 6.

After completion of study treatment, patients are followed up at 14 days.

#### Official Title

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A Phase II Clinical Trial of NEPA (Netupitant/Palonosetron) for Prevention of Chemotherapy Induced Nausea and Vomiting (CINV) in Patient Receiving the BEAM Conditioning Regimen Prior to Hematopoietic Cell Transplantation (HSCT)

#### Conditions ⓘ

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Malignant Neoplasm

#### Intervention / Treatment ⓘ

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- Drug: Netupitant
- Drug: Palonosetron Hydrochloride
- Other: Questionnaire Administration

#### Other Study ID Numbers ⓘ

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- NCI-2017-00548 ( Registry Identifier ) (REGISTRY: CTRP (Clinical Trial Reporting Program))
- STUDY00016288 ( Other Identifier ) (OTHER: OHSU Knight Cancer Institute)

#### Study Start (Actual) ⓘ

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2017-04-27

#### Primary Completion (Actual) ⓘ

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2020-02-20

#### Study Completion (Actual) ⓘ

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2020-03-20

#### Enrollment (Actual) ⓘ

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43

**Study Type** ⓘ

Interventional

**Phase** ⓘ

Phase 2

**Resource links provided by the National Library of Medicine**

[MedlinePlus](https://medlineplus.gov/) (<https://medlineplus.gov/>) related topics: [Nausea and Vomiting](https://medlineplus.gov/nauseaandvomiting.html) (<https://medlineplus.gov/nauseaandvomiting.html>)

[Drug Information](https://dailymed.nlm.nih.gov/dailymed/) (<https://dailymed.nlm.nih.gov/dailymed/>) available for:  
[Palonosetron](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Palonosetron) (<https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Palonosetron>) [Palonosetron hydrochloride](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Palonosetron+hydrochloride) (<https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Palonosetron+hydrochloride>)

[FDA Drug and Device Resources](https://clinicaltrials.gov/fda-links) (<https://clinicaltrials.gov/fda-links>)

## Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.


To learn more, please see the [Contacts and Locations section in How to Read a Study Record](https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations) (<https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations>).

This study has 1 location

### United States

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#### Oregon Locations

-  **Portland, Oregon, United States, 97239**  
OHSU Knight Cancer Institute

## Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies \(https://clinicaltrials.gov/study-basics/learn-about-studies\)](https://clinicaltrials.gov/study-basics/learn-about-studies).

## Eligibility Criteria

### Description

#### Inclusion Criteria:

- Subjects must be undergoing autologous or allogeneic hematopoietic stem cell transplant (HSCT) with the BEAM conditioning regimen prior to HSCT
- Eastern Cooperative Oncology Group (ECOG) performance status  $\leq$  2 or Karnofsky Performance Score  $\geq$  60%
- Able to swallow oral medications
- Ability to understand and the willingness to sign a written informed consent document

#### Exclusion Criteria:

- Subjects with known hypersensitivity or other allergic reactions attributed to compounds of similar biologic composition to netupitant, palonosetron, dexamethasone, or other agents used in the study
- Subjects who are receiving any other investigational agents or have received another investigational drug in the last 30 days
- Subjects who have had emesis or required antiemetics in the 48 hours prior to starting the BEAM conditioning regimen; patients required to take antipsychotics, appetite stimulants, or other medications with antiemetic effects will also be excluded if those medications cannot be replaced by therapeutic equivalents
- Female subjects who are pregnant, have a positive serum human chorionic gonadotrophin (hCG), or are lactating and intend to breastfeed a child; pregnant women are excluded from this study; breastfeeding should be discontinued if the mother is treated with NEPA
- Human immunodeficiency virus (HIV)-positive subjects on combination antiretroviral therapy are ineligible
- Subjects who have taken a neurokinin antagonist within 14 days prior to beginning the BEAM regimen
- Subjects who have a serum creatinine  $> 2 \times$  upper limit of normal (ULN)
- Subjects with severe renal failure or end stage renal disease (estimated GFR [glomerular filtration rate] of  $< 30$  mL/min) as estimated by the Cockcroft-Gault formula
- Subjects with severe hepatic insufficiency (Child Pugh score  $> 9$ )
- Subjects who have been reported  $> 5$  alcoholic drinks daily for the last year
- Subjects who have concurrent illness requiring systemic corticosteroid use other than the planned dexamethasone during conditioning therapy
- Subjects with gastrointestinal conditions that might result in malabsorption of the study drug
- Subjects with a history of anxiety-induced ("anticipatory") nausea and vomiting
- Subjects on strong CYP 3A4 inducers or inhibitors who are unable to have those agents replaced with clinical alternatives prior to beginning the study; length of washout period will be 7 days; notably, in the case of allogeneic transplant recipients requiring cyclosporine or

tacrolimus, no empiric dose adjustments will be required due to close level monitoring and adjustments, that are standard in Oregon Health & Science University (OHSU) protocols

- Subjects unable to discontinue benzodiazepines as antiemetics will not be allowed; additional antiemetics will be allowed for rescue but not for prophylaxis
- Subjects with personal or family history of QT prolongation, uncorrected electrolyte abnormalities, congestive heart failure, bradyarrhythmia, conduction disturbances and those taking antiarrhythmic medicinal products or other medicinal products that lead to QT prolongation or electrolyte abnormalities; relevant information will be collected as part of subject medical history

#### Ages Eligible for Study ?

18 Years and older (Adult, Older Adult )

#### Sexes Eligible for Study ?

All

#### Accepts Healthy Volunteers ?

No

## Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

### How is the study designed?

#### Design Details

**Primary Purpose** ? : Supportive Care

**Allocation** ? : N/A

**Interventional Model** ? : Single Group Assignment

**Masking** ? : None (Open Label)

Arms and Interventions

Participant Group/Arm ⓘ	Intervention/Treatment ⓘ
<p>Experimental: Supportive care (NEPA)</p> <p>Within 60 minutes before standard of care BEAM treatment, patients receive netupitant and palonosetron hydrochloride PO on days 1, 3, and 6.</p> <p>Netupitant: 300 mg, QD, Given PO Palonosetron Hydrochloride: 0.5 mg, QD, Given PO Questionnaire Administration: Ancillary studies</p>	<p>Drug: Netupitant</p> <ul style="list-style-type: none"> <li>• 300 mg, Given PO, QD</li> <li>• Other Names:                             <ul style="list-style-type: none"> <li>◦ CID6451149</li> <li>◦ D05152</li> <li>◦ RO 67-3189/000</li> </ul> </li> </ul> <p>Drug: Palonosetron Hydrochloride</p> <ul style="list-style-type: none"> <li>• 0.5 mg, Given PO, QD</li> <li>• Other Names:                             <ul style="list-style-type: none"> <li>◦ Aloxi</li> <li>◦ RS 25259-197</li> </ul> </li> </ul> <p>Other: Questionnaire Administration</p> <ul style="list-style-type: none"> <li>• Ancillary studies</li> </ul>

What is the study measuring?

Primary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame

Complete Response (CR) Defined as no Emesis and no Rescue Therapy	Number of subjects that reached a complete response (CR), defined as having no emesis and no rescue therapy.	Up to 5 days post chemotherapy
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Secondary Outcome Measures 

Outcome Measure	Measure Description	Time Frame
CR (Acute Phase)	Number of subjects that reached a complete response (CR), defined as having no emesis and no rescue therapy from 0 to 144 hours (acute phase) of the study drug administration.	Up to 144 hours post-study drug administration on day 1
CR (Delayed Phase)	Number of subjects that reached a complete response (CR), defined as having no emesis and no rescue therapy from 145 hours up to 264 hours (delayed phase) of the study drug administration.	From 145 hours up to 264 hours post-study drug administration on day 1

<p>Complete Protection (CP) Rate Defined as CR Plus no Nausea</p>	<p>Number of subjects that reached a complete response (CR), defined as having no emesis and no rescue therapy from 0 to 264 hours of the study drug administration.</p>	<p>Up to 264 hours post-study drug administration on day 1</p>
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Other Outcome Measures 

<p><b>Outcome Measure</b></p>	<p><b>Measure Description</b></p>	<p><b>Time Frame</b></p>
<p>Number of Participants With Emetic Episodes and Received Rescue Agents</p>	<p>The number of participants that had emetic episodes and received rescue agents (medications).</p>	<p>Up to 264 hours</p>
<p>Number of Participants With Emetic Episodes and Received Rescue Agents (Acute Phase)</p>	<p>The number of participants that had emetic episodes and received rescue agents (medications) (acute phase: for 0 to 144 hours timeframe of study drug administration)</p>	<p>Up to 144 hours post-study drug administration on day 1</p>
<p>Number of Participants With Emetic</p>	<p>The number of participants that had emetic episodes and received rescue agents</p>	<p>Up to 24 hours</p>

Episodes and Received Rescue Agents (Acute Phase)	(medications) (for 0 to 24 hours timeframe of study drug administration)	post-study drug administration on day 1
Number of Participants With Emetic Episodes and Received Rescue Agents (Delayed Phase)	The number of participants that had emetic episodes and received rescue agents (medications) during the delayed phase (for 145 hours up to 264 hours timeframe)	From 145 hours up to 264 hours post-study drug administration on day 1
Mean Levels of Nausea Per Day Assessed by Chemotherapy Induced Nausea and Vomiting Questionnaire	The mean level of nausea per day assessed by chemotherapy induced nausea and vomiting questionnaire. The full range of nausea level score on the questionnaire was from minimum value of 0 to a maximum value of 10. 0= no nausea or vomiting, and 10= worst nausea and vomiting. Higher score means a worse outcome.	Up to 11 days
Time to First Emesis and Time to Receiving First Rescue Medication	Will be depicted via Kaplan-Meier curves showing the percentage of patients who had no emesis or rescue medication use for the acute and delayed time periods.	Up to 264 hours

Time to Receiving First Rescue Medication and First Emesis	Will be depicted via Kaplan-Meier curves showing the percentage of patients who had no emesis or rescue medication use for the acute and delayed time periods.	Up to 264 hours
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## Collaborators and Investigators

This is where you will find people and organizations involved with this study.

### Sponsor ⓘ

#### OHSU Knight Cancer Institute

### Collaborators ⓘ

- Helsinn Therapeutics (U.S.), Inc
- Oregon Health and Science University

### Investigators ⓘ

- Principal Investigator: Joseph Bubalo, OHSU Knight Cancer Institute

## Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

## Study Registration Dates

**First Submitted** ⓘ

2017-03-27

**First Submitted that Met QC Criteria** ⓘ

2017-03-27

**First Posted** ⓘ

2017-03-31

## Results Reporting Dates

**Results First Submitted** ⓘ

2021-05-08

**Results First Submitted that Met QC Criteria** ⓘ

2021-05-08

**Results First Posted** ⓘ

2021-06-03

## [HHS Vulnerability Disclosure](#)

## Study Record Updates

**Last Update Submitted that met QC Criteria** ⓘ

2021-06-12

**Last Update Posted** ⓘ

2021-07-12

**Last Verified** ⓘ

2021-06

## More Information

### Terms related to this study

**Additional Relevant MeSH Terms**

Signs and Symptoms, Digestive  
Neoplasms  
Vomiting

Antiemetics  
Autonomic Agents  
Peripheral Nervous System Agents  
Physiological Effects of Drugs  
Gastrointestinal Agents  
Serotonin 5-HT3 Receptor Antagonists  
Serotonin Antagonists  
Serotonin Agents  
Neurotransmitter Agents  
Molecular Mechanisms of Pharmacological Action  
Palonosetron

## Drug and device information, study documents, and helpful links

### Studies a U.S. FDA-Regulated Drug Product

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Yes

### Studies a U.S. FDA-Regulated Device Product

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No

### Study Documents <sup>1</sup> Provided by Joseph Bubalo, OHSU Knight Cancer Institute

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- [Study Protocol and Statistical Analysis Plan \(https://cdn.clinicaltrials.gov/large-docs/88/NCT03097588/Prot\\_SAP\\_000.pdf\)](https://cdn.clinicaltrials.gov/large-docs/88/NCT03097588/Prot_SAP_000.pdf) [PDF, 1.25MB, 2018-11-27]