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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

HELSINN EXHIBIT 2022
Azurity Pharmaceuticals, Inc. v. Helsinn Healthcare S.A.
IPR2025-00945

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

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

Malignant Neoplasm

Intervention / Treatment

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

Other Study ID Numbers

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

Study Start (Actual)

2017-04-27

Primary Completion (Actual)

2020-02-20

Study Completion (Actual)

2020-03-20

Enrollment (Actual)

43

Study Type

Interventional

Phase

Phase 2

Resource links provided by the National Library of Medicine

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

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: 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)

FDA Drug and Device Resources (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).

This study has 1 location

United States

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).

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 =< 2 or Karnofsky Performance Score >= 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 x 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

Experimental: Supportive care (NEPA)
 	
Within 60 minutes before standard of care BEAM treatment, patients receive netupitant and palonosetron hydrochloride PO on days 1, 3, and 6.
 	
Netupitant: 300 mg, QD, Given PO Palonosetron Hydrochloride: 0.5 mg, QD, Given PO Questionnaire Administration: Ancillary studies
	Drug: Netupitant
	• 300 mg, Given PO, QD
	• Other Names:
	  ◦ CID6451149
	  ◦ D05152
	  ◦ RO 67-3189/000
	Drug: Palonosetron Hydrochloride
	• 0.5 mg, Given PO, QD
	• Other Names:
	  ◦ Aloxi
	  ◦ RS 25259-197
	Other: Questionnaire Administration
	• Ancillary studies

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

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

Complete Protection (CP) Rate Defined as CR Plus no Nausea	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.	Up to 264 hours post-study drug administration on day 1

Other Outcome Measures

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

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

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

Yes

Studies a U.S. FDA-Regulated Device Product

No

Study Documents **Provided by Joseph Bubalo, OHSU Knight Cancer Institute**

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