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Completed

An Efficacy and Safety Study of Intravenous Palonosetron Administered as an Infusion and as a Bolus for the Prevention of Nausea and Vomiting

ClinicalTrials.gov ID NCT02557035

Sponsor Helsinn Healthcare SA

Information provided by Helsinn Healthcare SA (Responsible Party)

Last Update Posted 2018-06-20

Study Details Tab

Study Overview

Brief Summary

PALO-15-17 is a clinical study assessing efficacy and safety of a single dose of palonosetron 0.25 mg administered as a 30-minute IV infusion compared to palonosetron 0.25 mg administered as a 30-second IV bolus (Aloxi, an antiemetic drug), both given with oral dexamethasone. The objective of the study is to demonstrate that infused IV palonosetron 0.25 mg is as effective as (non-inferior to) injected palonosetron IV 0.25 mg to prevent nausea and vomiting induced by highly emetogenic cancer chemotherapy in the 0-24 hours after administration of a single cycle of highly emetogenic chemotherapy

Official Title

A Phase 3, Single-dose, Multicenter, Randomized, Double-blind, Parallel Group Study to Assess the Efficacy and Safety of Palonosetron 0.25 mg Administered as a 30-minute IV Infusion Compared to

Feedback

HELSINN EXHIBIT 2030
Azurity Pharmaceuticals, Inc. v. Helsinn Healthcare S.A.
IPR2025-00946

Palonosetron 0.25 mg Administered as a 30-second IV Bolus for the Prevention of Chemotherapy-induced Nausea and Vomiting in Cancer Patients Receiving Highly Emetogenic Chemotherapy.

Conditions

Chemotherapy-Induced Nausea and Vomiting

Intervention / Treatment

- Drug: Palonosetron
- Drug: Dexamethasone

Other Study ID Numbers

Study Start

2015-10

Primary Completion (Actual)

2016-03

Study Completion (Actual)

2016-03

Enrollment (Actual)

441

Study Type

Interventional

Phase

Phase 3

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: Dexamethasone (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Dexamethasone) Dexamethasone sodium phosphate (https://dailymed.nlm.nih.gov/dailymed/search.cfm?

labeltype=human&query=Dexamethasone+sodium+phosphate) Dexamethasone acetate (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Dexamethasone+acetate) Palonosetron (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Palonosetron)

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 76 locations

Belarus

Lesnoy, Belarus, 223052
N.N. Aleksandrov Republican Research Oncology and Medical Radiology Center, Department of Chemotherapy

Minsk, Belarus, 220013
Minsk City Clinical Oncology Center

Bosnia and Herzegovina

Banja Luka, Bosnia and Herzegovina
University Clinical Centre of the Republic of Srpska

Bulgaria

Dobrich, Bulgaria, 9300
Multiprofile Hospital for Active Treatment, Dobrich, Department of Medical Oncology

Haskovo, Bulgaria, 6300
Specialized Hospital for Active Treatment in Oncology, Haskovo, Department of Medical Oncology

Plovdiv, Bulgaria, 4002
Multiprofile Hospital for Active Treatment "Central Onco Hospital", Plovdiv, Department of Medical Oncology

Rousse, Bulgaria, 7002
Complex Oncology Center, Ruse, Department of Medical Oncology

Sofia, Bulgaria, 1303
Multiprofile Hospital for Active Treatment "Serdika", Sofia, Department of Medical Oncology

Sofia, Bulgaria, 1431
University Multiprofile Hospital for Active Treatment "Sveti Ivan Rilski", Sofia, Department of Medical Oncology

Sofia, Bulgaria
Multiprofile Hospital for Active Treatment for Wonen's Health "Nadezhda"

Varna, Bulgaria, 9010
Hospital for Active Treatment of Oncological Diseases "Dr. Marko Antonov Markov", Varna, Department of Medicinal Oncology and Palliative Care

Varna, Bulgaria, 9010
Multiprofile Hospital for Active Treatment "Sveta Marina", Varna, Clinic of Medical Oncology

Georgia

Tbilisi, Georgia, 0131
JSC NeoMedi

Tbilisi, Georgia, 0159
LTD Institute of Clinical Oncology

Tbilisi, Georgia, 0160
LTD Aversi Clinic

Tbilisi, Georgia
LDT High Technology Medical Center University Clinic

Greece

Athens, Greece
"Sotiria" Chest Diseases Hospital of Athens

Thessaloniki, Greece, 570 01
Thermi Clinic S.A.

Thessaloniki, Greece, 570 10
General Hospital of Thessaloniki "G. Papanikolaou", University Department of Pulmonology

Thessaloniki, Greece
Bioclinic Thessalonikis S.A.

Hungary

Budapest, Hungary, 1121
Koranyi National Institute of TBC and Pulmonology

Budapest, Hungary, 1145
Uzsoki Hospital, Department of Radiation Oncology

Debrecen, Hungary
University of Debrecen, Medical and Health Science Center

Gyor, Hungary, 9024
Petz Aladar County Teaching Hospital, Center for Oncoradiology

Kaposvár, Hungary, 7400
Kaposi Mor Teaching Hospital, Centre for Clinical Oncology

Miskolc, Hungary, 3526
Borsod-Abauj-Zemplen County Hospital and University Educational Hospital

Nyíregyháza, Hungary
Szabolcs-Szatmar-Bereg County Hospitals and University Teaching Hospital

Pecs, Hungary
Medical Center of the University of Pecs

Lithuania

Kaunas, Lithuania, 45434
Hospital of Lithuanian University of Health Sciences Kaunas Clinics, Oncology Hospital, Department of Conservative Oncology

Kaunas, Lithuania, 50009
Hospital of Lithuanian University of Health Sciences Kaunas Clinics, Clinic of Oncology and Hematology

Romania

Baia Mare, Romania
Oncopremium Team SRL, Department of Oncology

Bucharest, Romania, 022328
Prof. Dr. Alexandru Trestioreanu Institute of Oncology, Medical Oncology Department II

Bucharest, Romania, 030171
Coltea Clinical Hospital, Department of Medical Oncology

Bucharest, Romania, 031864
Hifu Terramed Conformal SRL, Department of Medical Oncology

Bucharest, Romania
Ianuli Med Consult SRL, Oncology Department

Cluj-Napoca, Romania, 400015
"Prof. Dr. Ion Chiricuta" Institute of Oncology, Radiotherapy Department I

Cluj-Napoca, Romania
Radiotherapy Center Cluj SRL, Department of Oncology

Constanta, Romania, 900591
Constanta Emergency Clinical County Hospital, Department of Medical Oncology

Craiova, Romania
Oncology Center "Sf. Nectarie", Department of Medical Oncology

Suceava, Romania, 720237
Suceava Sf. Ioan cel Nou Emergency County Hospital, Department of Medical Oncology

Timisoara, Romania, 300239
Oncomed SRL, Department of Medical Oncology

Timisoara, Romania
Oncocenter Clinical Oncology SRL, Department of Medical Oncology

Russian Federation

Arkhangelsk, Russian Federation
Arkhangelsk Clinical Oncology Center

Barnaul, Russian Federation
Altay Territorial Oncology Center

Bryansk, Russian Federation
Bryansk Regional Oncology Center

Chelyabinsk, Russian Federation

Chelyabinsk Regional Clinical Oncology Center

Chelyabinsk, Russian Federation
Evimed, LLC

Ekaterinburg, Russian Federation
Sverdlovsk Regional Oncology Center

Ivanovo, Russian Federation
Ivanovo Regional Oncology Center

Kaluga, Russian Federation
Kaluga Regional Oncology Center

Kazan, Russian Federation
Republican Clinical Oncology Center

Krasnoyarsk, Russian Federation
Krasnoyarsk A.I. Kryzhanovsky Regional Oncology Center

Moscow, Russian Federation
Moscow City Oncology Hospital #62

Moscow, Russian Federation
Moscow Clinical Scientific and Practical Center

Moscow, Russian Federation
N.N. Blokhin Russian Oncology Research Center, Surgery Dept. 2

Moscow, Russian Federation
N.N. Blokhin Russian Oncology Research Center, Surgery Dept. of Female Reproductive System Tumors

Moscow, Russian Federation
N.N. Blokhin Russian Oncology Research Center

Nizhny Novgorod, Russian Federation
Branch #1 of Nizhny Novgorod Regional Oncology Center

Novosibirsk, Russian Federation
City Clinical Hospital #1

Novosibirsk, Russian Federation
Novosibirsk Regional Oncology Center

Omsk, Russian Federation
Clinical Oncology Center, Dept. of Chemotherapy

Omsk, Russian Federation
Clinical Oncology Center

Orenburg, Russian Federation
Orenburg Regional Clinical Oncology Center

Pyatigorsk, Russian Federation
Pyatigorsk Oncology Center

Ryazan, Russian Federation
Regional Clinical Oncology Center

Samara, Russian Federation
Samara Regional Clinical Oncology Center

St. Petersburg, Russian Federation
City Clinical Oncology Center, Thoracic Oncology Dept.

St. Petersburg, Russian Federation
City Clinical Oncology Center, Urology Oncology Dept.

St. Petersburg, Russian Federation
City Clinical Oncology Center

St. Petersburg, Russian Federation
First I.P. Pavlov State Medical University of St. Petersburg

St. Petersburg, Russian Federation
St.Petersburg Municipal Clinical Oncology Center

Tambov, Russian Federation
Tambov Regional Oncology Center

Tomsk, Russian Federation
Tomsk Research Institute of Oncology, General Oncology Dept.

Tomsk, Russian Federation
Tomsk Research Institute of Oncology

Ufa, Russian Federation
Republican Clinical Oncology Center

Veliky Novgorod, Russian Federation
Regional Clinical Oncology Center

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:

- Signed written informed consent
- Histologically or cytologically confirmed solid tumor malignancy.
- Naïve to cytotoxic chemotherapy. Previous biological or hormonal therapy will be permitted.
- Scheduled to receive first course of one of the following reference HEC, alone or in combination with other chemotherapeutic agents on Day 1:
    - cisplatin administered as a single IV dose of ≥ 70 mg/m2
    - cyclophosphamide ≥1500 mg/m2
    - carmustine (BCNU) >250 mg/m2
    - dacarbazine (DTIC)
    - mechloretamine (nitrogen mustard)
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2 .
- If a patient is female, she shall be of non-childbearing potential or of childbearing potential using reliable contraceptive measures and having a negative urine pregnancy test.
- Hematologic and metabolic status adequate for receiving an highly emetogenic regimen based on laboratory criteria (Total Neutrophils,Platelets, Bilirubin, Liver enzymes, Serum Creatinine or Creatinine Clearance)
- Able to read, understand, follow the study procedure and complete patient diary.

Exclusion Criteria:

- Lactating woman.
- Current use of illicit drugs or current evidence of alcohol abuse.
- Scheduled to receive moderately emetogenic chemotherapy or highly emetogenic chemotherapy from Day 2 to Day 5.
- Received or is scheduled to receive radiation therapy to the abdomen or the pelvis within 1 week prior to the start of the reference HEC administration on Day 1 or between Days 1 to 5.
- Any vomiting, retching, or nausea (grade ≥ 1 as defined by National Cancer Institute) within 24 hours prior to the start of the reference HEC administration on Day 1.
- Symptomatic primary or metastatic CNS malignancy.
- Active peptic ulcer disease, gastrointestinal obstruction, increased intracranial pressure, hypercalcemia, an active infection or any illness or medical conditions (other than malignancy) that, in the opinion of the Investigator, may confound the results of the study, represent another potential etiology for emesis and nausea (other than chemotherapy-induced nausea and vomiting) or pose unwarranted risks in administering the study drugs to the patient.
- Known hypersensitivity or contraindication to 5-HT3 receptor antagonists
- Known contraindication to the IV administration of 50 mL 5% glucose solution.

- Participation in a previous clinical trial involving palonosetron.
- Any investigational drugs (other than those given in this study) taken within 4 weeks prior to Day 1, and/or is scheduled to receive any investigational drug during the present study.
- Systemic corticosteroid therapy at any dose within 72 hours prior to the start of the reference HEC administration on Day 1. However, topical and inhaled corticosteroids are permitted.
- Scheduled to receive bone marrow transplantation and/or stem cell rescue therapy.
- Any medication with known or potential antiemetic activity within 24 hours prior to the start of the reference HEC administration on Day 1, including but not limited to 5-HT3 receptor antagonists and NK-1 receptor antagonists
- Concurrent medical condition that would preclude administration of dexamethasone for 4 days such as systemic fungal infection or uncontrolled diabetes.

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 : Prevention
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: I.V. palonosetron infusion plus dexamethasone Intravenous palonosetron (Aloxi 0.25 mg solution for injection) as an infusion with oral dexamethasone, both given on Day 1, prior to the scheduled start of cisplatin; then dexamethasone from Days 2 through 4.	Drug: Palonosetron Drug: Dexamethasone
Active Comparator: I.V. palonosetron bolus plus dexamethasone Intravenous palonosetron (Aloxi 0.25 mg solution for injection) as a bolus with oral dexamethasone, both given on Day 1, prior to the scheduled start of cisplatin; then dexamethasone from Days 2 through 4.	Drug: Palonosetron Drug: Dexamethasone

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Patients With Complete Response (CR) Defined as no Emesis, no Rescue Medication, in the Acute Phase		0-24 hours

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Patients With Complete Response (CR) Defined as no Emesis, no Rescue Medication, in the Delayed Phase		>24-120 hours
Percentage of Patients With Complete		0-120 hours

Response (CR) Defined as no Emesis, no Rescue Medication, in the Overall Phase		
Percentage of Patients With no Emetic Episodes in the Acute Phase		0-24 hours
Percentage of Patients With no Emetic Episodes in the Delayed Phase		>24-120 hours
Percentage of Patients With no Emetic Episodes in the Overall Phase		0-120 hours
Percentage of Patients With no Rescue Medication in the Acute Phase		0-24 hours
Percentage of Patients With no Rescue Medication in		>24-120 hours

the Delayed Phase		
Percentage of Patients With no Rescue Medication in the Overall Phase		0-120 hours

Collaborators and Investigators

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

Sponsor

Helsinn Healthcare SA

Collaborators

- PSI CRO

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

2015-09-21

First Submitted that Met QC Criteria

2015-09-21

First Posted (Estimated)

2015-09-22

Results Reporting Dates

Results First Submitted

2018-05-09

Results First Submitted that Met QC Criteria

2018-06-18

Results First Posted

2018-06-20

Certification/Extension Dates

Certification/Extension First Submitted

2016-03-23

Certification/Extension First Submitted that Met QC Criteria

2016-03-23

Certification/Extension First Posted (Estimated)

2016-04-26

Study Record Updates

Last Update Submitted that met QC Criteria

2018-06-18

Last Update Posted

2018-06-20

Last Verified

2018-06

More Information

Terms related to this study

Additional Relevant MeSH Terms

Signs and Symptoms, Digestive
Nausea
Vomiting

Anti-Inflammatory Agents
Antiemetics
Autonomic Agents
Peripheral Nervous System Agents
Physiological Effects of Drugs
Gastrointestinal Agents
Glucocorticoids
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Antineoplastic Agents, Hormonal
Antineoplastic Agents

HHS Vulnerability Disclosure

Serotonin 5-HT3 Receptor Antagonists
Serotonin Antagonists
Serotonin Agents
Neurotransmitter Agents
Molecular Mechanisms of Pharmacological Action
Dexamethasone
Palonosetron