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Completed

An Efficacy and Safety Study of Oral and Intravenous Palonosetron for the Prevention of Nausea and Vomiting

ClinicalTrials.gov ID NCT01363479

Sponsor Helsinn Healthcare SA

Information provided by Helsinn Healthcare SA (Responsible Party)

Last Update Posted 2021-09-22

Study Details Tab

Study Overview

Brief Summary

PALO-10-01 is a clinical study assessing efficacy and safety of a single oral dose of palonosetron compared to a single intravenous dose of palonosetron (Aloxi, an antiemetic drug), both given with oral dexamethasone. The objective of the study is to demonstrate that oral palonosetron 0.50 mg is as effective as (non-inferior to) 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

Single-dose, Multicenter, Randomized, Double-blind, Double-dummy, Parallel Group Study to Assess the Efficacy and Safety of Oral Palonosetron 0.50 mg Compared to I.V. Palonosetron 0.25 mg Administered With Dexamethasone for the Prevention of Chemotherapy-induced Nausea and Vomiting in Cancer Patients Receiving Highly Emetogenic Cisplatin-based Chemotherapy

HELSINN EXHIBIT 2019
Azurity Pharmaceuticals, Inc. v. Helsinn Healthcare S.A.
IPR2025-00947

Conditions

Chemotherapy-Induced Nausea and Vomiting

Intervention / Treatment

- Drug: Oral palonosetron
- Drug: I.V. palonosetron
- Drug: Dexamethasone

Other Study ID Numbers

Study Start

2011-07

Primary Completion (Actual)

2012-11

Study Completion (Actual)

2012-11

Enrollment (Actual)

743

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 79 locations

United States

Arkansas Locations

Hot Springs, Arkansas, United States, 71913
Genesis Cancer Centre

California Locations

Corona, California, United States, 92879
Compassionate Cancer Center

Fountain Valley, California, United States, 92708
Compassionate Cancer Centre Medical Group

Mission Hills, California, United States, 91345
Facey Medical Group

Riverside, California, United States, 92501
Compassionate Cancer Care Medical Group

Ohio Locations

Middletown, Ohio, United States, 45042
Signal Point Clinical Research Center, LLC

Rhode Island Locations

Bristol, Rhode Island, United States, 37620
Wellmont Medical Associates-Oncology and Hematology

South Carolina Locations

Charleston, South Carolina, United States, 29414
Charleston Hematology Oncology

Utah Locations

Ogden, Utah, United States, 84403
Northern Utah Associates [Hematology/ Oncology]

Argentina

Cordoba, Argentina, X5006HBF
Instituto Oncológico de Córdoba (IONC)

Córdoba, Argentina, X5004FHP
Clínica Universitaria Reina Fabiola

Quilmes, Argentina, B1878DVB
Instituto Médico CER [Oncology]

Rosario, Argentina, 2000
Sanatorio Parque

San Miguel de Tucuman, Argentina, T4000AIK
Centro Medico San Roque

Santa Fe, Argentina, 3000
ISIS Clinica Especializada

Buenos Aires Locations

Mar del Plata, Buenos Aires, Argentina, 7600
Centro Oncológico Integral (COI)

Bulgaria

Gabrovo, Bulgaria, 5300
MHAT Dr. Tota Venkova

Sofia, Bulgaria, 1233
Specialized Hospital for Active Treatement of Oncology Diseases - Sofia District Medical Oncology Department

Sofia, Bulgaria, 1572
UMHAT "Tsaritsa Yoanna - ISUL" Ltd.Medical Oncology Clinic

Sofia, Bulgaria, 1756

Specialised Hospital for Active treatment on Oncology

Sofia, Bulgaria, 6300
District Dispensery for Oncology Diseases with in-patient

Stara Zagora, Bulgaria, 6003
Complex Oncology Centre

Croatia

Osijek, Croatia, 31000
Klinicki bolnicki centar [Oncology]

Rijeka, Croatia, 51000
KBC Rijeka

Varazdin, Croatia, 42000
Opca bolnica Varazdin

Zagreb, Croatia, 10000
KBC Zagreb

Zagreb, Croatia, 10000
Klinicka bolnica [Sestre milosrdnice]

Germany

Berlin, Germany, 10117
Klinik und Poliklinik für Onkologie und Hämatologie Universitätsmedizin Charité Mitte

Hamburg, Germany, 22081
OncoResearch Lerchenfeld UG

München, Germany, 81545
Städtisches Klinikum München

München, Germany, 81737
Staedtisches Krankenhaus Muenchen Neuperlach

Hungary

Budapest, Hungary, 1125
Semmelweis Egyetem Kútvölgyi Klinikai Tömb

Budapest, Hungary, 1145
Fővárosi Önkormányzat Uzsoki utcai Kórház

Györ, Hungary, 9024
Petz Aladár Megyei Oktató Kórház

Kecskemet, Hungary, 6000
Bács-Kiskun Megyei Önkormányzat Kórháza, Szeged

Pécs, Hungary, 7624
Pécsi Tudományegyetem [Onkoterápiás Intézet]

Szolnok, Hungary, 5004
Jasz-Nagykun-Szolnok Megyei Hetenyi Geza Korhaz

India

Bangalore, India, 560068
Sri Venkateshwara Hospital [Medical Oncology]

Bangalore, India, 632004
Chinmaya Mission Hospital

Vijayawada, India, 520002
City Cancer Centre [Surgical and Medical Oncology]

Andhra Pradesh Locations

Hyderabad, Andhra Pradesh, India, 500 082
Yashoda Super speciality Hospital

Maharashtra Locations

Pune, Maharashtra, India, 444605
Sujan Surgical Cancer Hospital and Amracvati Cancer Foundation

Tamil Nadu Locations

Chennai, Tamil Nadu, India, 600035
Apollo Speciality Hospital

Italy

Brescia, Italy, 25124
Fondazione Poliambulanza Istituto Ospedaliero

Lecce, Italy, 73100
Ospedale Vito Fazzi - ASL Lecce

Lecco, Italy, 23900
Presidio Ospedaliero "Alessandro Manzoni"

Potenza, Italy, 85100
AO Regionale S.Carlo di Potenza

Poland

Elblag, Poland, 82-300
Szpital Wojewodzki Zespolony

Lodz, Poland, 93-509

Wojewodzki Szpital Specjalistyczny im. M.Kopernika

Lomza, Poland, 18-400
Szpital Wojewodzki w Lomzy im. Kardynala S. Wyszynskiego

Slupsk, Poland, 76-200
Wojewodzki Szpital Specjalistyczny im. J. Korczaka

Warszawa, Poland, 02-781
Centrum Onkologii - Instytut im. Marii Sklodowskiej - Curie

Warszawa, Poland, 04-125
NZOZ Magodent - Centrum Medczyne Ostrobramska

Romania

Baia-Mare, Romania, 430031
Spitalul Judetean de Urgenta "Dr. Constantin Opris"

Bucharest, Romania, 22328
Institutul Oncologic "Prof. Dr. Alex. Trestioreanu"

Cluj-Napoca, Romania, 400015
Institutul Oncologic "Prof. Dr. Ion Chiricuta"

Cluj-Napoca, Romania, 400349
Spitalul Clinic Judetean de Urgenta Cluj (Oncologie Medicala)

Iasi, Romania, 700106
Centrul de Oncologie Euroclinic

Iasi, Romania, 700483
Institutul Regional de Oncologie Iasi

Sibiu, Romania, 550245
Spitalul Clinic Judetean de Urgenta Sibiu [Oncologie]

Timisoara, Romania, 300239
Oncomed SRL

Russian Federation

Arkhangelsk, Russian Federation, 163045
GUZ Arkhangelsk Regional Clinical Oncological Dispensary

Krasnoyarsk, Russian Federation, 660022
GOU VPO Krasnoyarsk State Medical University n.a. prof. V.F.

Lipetsk, Russian Federation, 398005
GUZ Lipetsk Regional Oncology Dispensary [General Oncology]

Magnitogorsk, Russian Federation, 455001
GUZ Regional Oncology Dispensary #2

Moscow, Russian Federation, 115478
RAMN - Russian Cancer Research Center

Moscow, Russian Federation, 115478
Russian Oncology Research Center n.a. N.N. Blokhin RAMN

Novosibirsk, Russian Federation, 630047
MBUZ City Clinical Hospital #1 [Oncology]

Obninsk, Russian Federation, 249036
FGBU "Medical Radiology Scientific Center of Minzdravsotsrazvitiya RF

Ryazan, Russian Federation, 390026
Ryazan State Med. Univer. n.a. I.I.Pavlov based Ryazan Regio

Saint Petersburg, Russian Federation, 188663
GUZ Leningrad Regional Oncological Dispensary

Saint Petersburg, Russian Federation, 197022
St. Petersburg Clinical Oncology Dispesary

Ukraine

Chernihiv, Ukraine, 14029
Komunalnyi likuvalno-profilaktychnyi zaklad "Chernigivskyi

Dnipropetrovsk, Ukraine, 49102
Komunalnyi zaklad Miska bahatoprofilna klinichna likarnia #4

Donetsk, Ukraine, 83092
Komunalno-klinichnyi likuvalno-profilaktychnyi zaklad

Kharkiv, Ukraine, 61024
DU IMR AMNU [vd khemter]

Kharkiv, Ukraine, 61070
Kharkivskyi oblasnyi onkologichnyi klinichnyi tsentr

Khmelnytskyi, Ukraine, 29009
Chmelnytskyi Regional Clinical Oncology Centre [Oncology]

Uzhgorod, Ukraine, 88000
Uzhgorod National University

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:

- Naïve to cytotoxic chemotherapy. Previous biological or hormonal therapy is permitted.
- Diagnosed with a malignant solid tumor and scheduled to receive first course of cytotoxic chemotherapy with cisplatin administered as a single I.V. dose of equal or more than 70 mg/m2 over 1-4 hours on study Day 1, either alone or in combination with other chemotherapeutic agents.
- If scheduled to receive combination regimens, non-cisplatin agents of moderate to high emetogenic potential are allowed and they must be administered following the cisplatin infusion and completed no more than 6 hours after the initiation of cisplatin infusion.
- If scheduled to receive chemotherapy agents of minimal to low emetogenic potential, they are to be given on Day 1 following cisplatin or on any subsequent study day.
- ECOG Performance Status of 0, 1, or 2
- Female patients of either non-childbearing potential or child-bearing potential with a commitment to use contraceptive methods throughout the clinical trial
- Hematologic and metabolic status adequate for receiving a highly emetogenic cisplatin-based regimen based on laboratory criteria (Neutrophils,Platelets, Bilirubin, Liver enzymes, Serum Creatinine or Creatinine Clearance)
- If a patient has a known hepatic or renal impairment, he/she may be enrolled in this study at the discretion of the Investigator.
- If a patient has a known history or predisposition to cardiac conduction interval abnormalities he/she may be enrolled in this study at the discretion of the Investigator.

Exclusion Criteria:

- If female, pregnant or lactating.
- Current use of illicit drugs or current evidence of alcohol abuse.
- Scheduled to receive moderately emetogenic chemotherapy (MEC) or HEC from Day 2 to Day 5 following cisplatin administration.
- Received or is scheduled to receive radiation therapy to the abdomen, or the pelvis within 1 week prior to Day 1 or between Days 1 to 5.
- Any vomiting, retching, or mild nausea within 24 hours prior to Day 1.
- Symptomatic primary or metastatic CNS malignancy.
- Active peptic ulcer disease, gastrointestinal obstruction, increased intracranial pressure, hypercalcemia, an active infection or any uncontrolled 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, CINV) or pose unwarranted risks in administering the study drugs to the patient.

- Known hypersensitivity or contraindication to 5-HT3 receptor antagonists (e.g., palonosetron, ondansetron, granisetron, dolasetron, tropisetron, ramosetron) or dexamethasone.
- Participation in a 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 study.
- Systemic corticosteroid therapy at any dose within 72 hours prior to Day 1. However topical and inhaled corticosteroids with a steroid dose of £ 10 mg of prednisone daily or its equivalent 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 Day 1

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: Oral palonosteron plus dexamethasone Oral palonosetron (Aloxi 0.50 mg softgel capsule) with oral dexamethasone, both given on Day 1, prior to the scheduled start of cisplatin; then dexamethasone from Days 2 through 4.	Drug: Oral palonosetron Drug: Dexamethasone
Active Comparator: I.V. palonosetron plus dexamethasone Intravenous palonosetron (Aloxi 0.25 mg solution for injection) with oral dexamethasone, both given on Day 1, prior to the scheduled start of cisplatin; then dexamethasone from Days 2 through 4.	Drug: I.V. 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		0-24 hours

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Patients With no Emesis		0-24 hours
Percentage of Patients With no Rescue Medication		0-24 hours

Collaborators and Investigators

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

Sponsor

Helsinn Healthcare SA

Collaborators

- Parexel

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

2011-05-30

First Submitted that Met QC Criteria

2011-05-31

First Posted (Estimated)

2011-06-01

Results Reporting Dates

Results First Submitted

2014-11-06

Results First Submitted that Met QC Criteria

2014-11-06

Results First Posted (Estimated)

2014-11-17

Certification/Extension Dates

Certification/Extension First Submitted

2013-01-16

Certification/Extension First Submitted that Met QC Criteria

2013-01-16

Certification/Extension First Posted (Estimated)

2013-01-28

Study Record Updates

Last Update Submitted that met QC Criteria

2021-08-30

HHS Vulnerability Disclosure

Last Update Posted

2021-09-22

Last Verified

2021-08

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