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Completed

A Safety Study of Oral Netupitant and Palonosetron for the Prevention of Nausea and Vomiting

ClinicalTrials.gov ID NCT01376297

Sponsor Helsinn Healthcare SA

Information provided by Helsinn Healthcare SA (Responsible Party)

Last Update Posted 2014-11-17

Study Details Tab

Study Overview

Brief Summary

NETU-10-29 is a clinical study assessing safety of netupitant and palonosetron, two antiemetic drugs, both given with oral dexamethasone. The objective of the study is to evaluate if netupitant and palonosetron are safe when administered to prevent nausea and vomiting after administration of repeated cycles of chemotherapy.

Official Title

A Phase III, Multicenter, Randomized, Double-blind, Unbalanced (3:1) Active Control Study to Assess the Safety and Describe the Efficacy of Netupitant and Palonosetron for the Prevention of Chemotherapy-induced Nausea and Vomiting in Repeated Chemotherapy Cycles.

Conditions

Feedback

HELSINN EXHIBIT 2018
Azurity Pharmaceuticals, Inc. v. Helsinn Healthcare S.A.
IPR2025-00946

Chemotherapy-Induced Nausea and Vomiting

Intervention / Treatment

- Drug: Netupitant and Palonosetron
- Drug: Aprepitant
- Drug: Palonosetron
- Drug: Dexamethasone

Other Study ID Numbers

Study Start

2011-07

Primary Completion (Actual)

2012-09

Enrollment (Actual)

413

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)
Palonosetron (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Palonosetron)
Aprepitant (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Aprepitant)

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 75 locations

United States

Alabama Locations

Muscle Shoals,, Alabama, United States, 35661
Northwest Alabama Cancer Center PC

California Locations

Burbank, California, United States, 91505
East Valley Hematology and Oncology Medical Group

Los Angeles, California, United States, 90017
American Institute of Research

New Jersey Locations

East Orange, New Jersey, United States, 07018
Veterans Administration New Jersey Health Care System

New York Locations

Nyack, New York, United States, 10960
Hematology Oncology Associates of Rockland

Ohio Locations

Canton, Ohio, United States, 44708
Hematology and Oncology Associates, Inc.

Massillon, Ohio, United States, 44646
Tri-County Hematology & Oncology Associates, Inc

Rhode Island Locations

Pawtucket, Rhode Island, United States, 02860
Cancer Center at Memorial Hospital of RI

South Carolina Locations

Spartanburg, South Carolina, United States, 29303
Spartanburg Regional Health Services

Texas Locations

Corpus Christi, Texas, United States, 78405
South Texas Comrehensive Cancer Centers

Houston, Texas, United States, 77030-4009
MD Anderson Cancer Center

Bulgaria

Pleven, Bulgaria, 5800
UMHAT "Dr. Georgi Stranski"

Shumen, Bulgaria, 9700
Complex Oncology Center - Shumen Ltd. [Oncology]

Tarnovo, Bulgaria, 5000
COC - Veliko Tarnovo Dept. Medical Oncology

Varna, Bulgaria, 9010
Specialized Hospital for Active Treatment in Oncology "Dr. Marko Markov" Varna

Vratsa, Bulgaria, 3000
COC - Vratsa Dept. of Palliative Care

Czech Republic

Mlada Boleslav, Czech Republic, 293 50
Oblastni nemocnice Mlada Boleslav a.s., Onkologie

Nymburk, Czech Republic, 288 01
AVICENNUS s.r.o. Onkologie Nymburk

Praha 5, Czech Republic, 150 06
Fakultni nemocnice v Motole

Praha 5, Czech Republic, 150 30

Nemocnice Na Homolce, Oddeleni klinicke onkologie

Znojmo, Czech Republic, 669 02
Nemocnice Znojmo, p.o.

Germany

Augsburg, Germany, 86150
Gemeinschaftspraxis, Dr. Med O.Brundler und B.Heinreich, PD Dr. med M.Bangerter Fachärzte für Innere Medizin, Hämatologie und internistische Onkologie

Berlin, Germany, 12200
Charite - Campus Benjamin Franklin (CBF)

Berlin, Germany, 13347
Medizinisches Versorgungszentrum für Hämatologie und Tumorerkrankungen, HIV/AIDS und Hepatitiden

Dresden, Germany, 01307
Universitaetsklinikum Carl Gustav Carus

Duisburg, Germany, 47166
St. Johannes Hospital Medizinische Klinik II, Hämatologie, Onkologie und klinische Immunologie

Freiburg, Germany, 79106
Praxis Fuer Interdisziplinaere Onkologie und Haematologie

Hannover, Germany, 30625
Medizinische Hochschule, Zentrum für Innere Medizin, Klinik für Hämatologie, Hämostaseologie, Onkologie und Stammzelltransplantation

Hennigsdorf, Germany, 16761
Ärzteforum Hennigsdorf

Marburg, Germany, 35037
Praxis für Innere Medizin, Hämatologie und Internistische Onkologie

Mönchengladbach, Germany, 41062
Krankenhaus, Maria Hilf, St. Franziskus Innere Medizin

Regensburg, Germany, 93053
OncoPRO GbR Dr. R. Dengler, Dr. A. Kröber

Hungary

Budapest, Hungary, 1122

Országos Onkológiai Intézet, B. Belgyógyászati Osztály

Gyula, Hungary, 5700
Bekes Megyei Kepviselo-testulet Pandy Kalman Korhaz

Kaposvár, Hungary, 7400
Kaposi Mor Oktato Korhaz [Klinikai Onkologiai Centrum]

Miskolc, Hungary, 3501
Borsod-Abaúj-Zemplén Megyei Kórház és Egyetemi Oktatók

Szentes, Hungary, 6600
Dr. Bugyi Istvan Korhaz [Oncology]

Székesfehérvár, Hungary, 8000
Fejér Megyei Szent György Kórház [Onkológiai Osztály]

India

Chennai, India, 600010
Kumaran Hospital PVT Ltd

Chennai, India, 600018
Dr.Rai Memorial Medical centre

Cuttack, India, 753007
Acharya Harihara Regional Cancer Centre [Oncology]

Gujarat, India, 388325
M.S Patel Cancer Hospital [Oncology]

Hubli, India, 580025
Research Unit, The Karnatak cancer therapy & Research Instit

Jaipur, India, 302016
S.M.S College And Hospital

Madurai, India, 625020
Apollo Speciality Hospital [Oncology]

Uttar Pradesh, India, 226001
Lucknow Cancer Institute [Oncology]

Visakhapatnam, India, 530002
King George Hospital [Medical Oncology]

Poland

Bialystok, Poland, 15-027
Bialostockie Centrum Onkologii im.

M.Sklodowskiej-Curie im dr. E.Pileckiej z Pododdzialem Chemioterapii Dziennej

Lublin, Poland, 20-090
Centrum Onkologii Ziemi Lubelskiej im.Sw.Jana z Dukli III Oddzial Onkologii Ginekologicznej, Radioterapii I Chemioterapii

Poznan, Poland, 60-535
Ginekologiczno-Położniczy Szpital Kliniczny UM w Poznaniu

Poznan, Poland, 60-569
Szpital Kliniczny Przemienienia Panskiego UM w Poznaniu

Poznan, Poland, 61-866
Wielkopolskie Centrum Onkologii im. M. Sklodowskiej-Curie i Onkologii Ginekologicznej

Prabuty, Poland, 82-550
Szpital Specjalistyczny

Raciborz, Poland, 47-400
Szpital Rejonowy im. dr J. Rostka w Raciborzu

Russian Federation

Chelyabinsk, Russian Federation, 454087
GBUZ "Cheliabinsky Regional Oncology Dispensary"

Kazan, Russian Federation, 420029
GAUZ Republican Clinical Oncology Dispensary of Minzdrav of Republic of Tatarstan

Moscow, Russian Federation, 129128
Non-State healthcare Indtitution Central Clinical Hospital # 2 named after N.A. Semashko OAO "RZhD"

Novgorod, Russian Federation, 603001
FBUZ Privolzhsky District Medical Center of FMBA

Orel, Russian Federation, 302020
Regional GUZ Orlovskiy Oncological Dispensary

Saint-Petersburg, Russian Federation, 197022
GBOU VPO "Saint-Petersburg State Medical University

St. Petersburg, Russian Federation, 191104
GUZ Leningradskiy Regional Oncology Dispensary

Tula, Russian Federation, 300040

GUZ Tula Regional Oncological Dispensary [Oncology]

Tyumen, Russian Federation, 625041
GBUZ Tyumen Regional Oncology Dispensary

Ufa, Russian Federation, 450054
GBUZ Republican Clinical Oncology Dispensary of Minzdrav of Republic of Bashkortostan

Serbia

Belgrade, Serbia, 11000
Clinical Hospital Center Bezanijska Kosa

Beograd, Serbia, 11000
Institute of oncology and radiology of Serbia

Kragujevac, Serbia, 34000
Clinical Center Kragujevac

Ukraine

Chernivtsi, Ukraine, 58013
Chernivtsi Regional Cancer Hospital [Outpatient Department]

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

Dnipropetrovsk, Ukraine, 49100
KZ MKL19, MOTsr, vd khimter [viddilennia khimioterapii]

Donetsk, Ukraine, 83092
KKLPZ DnOPTsr [radio vd#3]

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

Poltava, Ukraine, 36011
Poltavskyi oblasnyi klinichnyi onkolohichnyi dyspanser Pol

Uzhgorod, Ukraine, 88014
Zakarpatskyi oblasnyi klinichnyi onkodyspanser [viddilennia

Zaporizhia, Ukraine, 69040
ZaOKOD [abdom vd]

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.
- Naïve to cytotoxic chemotherapy. Previous biological or hormonal therapy is permitted.
- Diagnosed with a malignant tumor.
- If scheduled to receive repeated consecutive courses of chemotherapy, a single dose of one or more of the following agents administered on Day 1 is allowed:
    - Highly emetogenic chemotherapy: any I.V. dose of cisplatin, mechlorethamine, streptozocin, cyclophosphamide more or equal to 1500 mg/m2, carmustine, dacarbazine;
    - Moderately emetogenic chemotherapy: any I.V. dose of oxaliplatin, carboplatin, epirubicin, idarubicin, ifosfamide, irinotecan, daunorubicin, doxorubicin, cyclophosphamide I.V. (less than 1500 mg/m2), cytarabine I.V. (more than 1 g/m2), azacidine, alemtuzumab, bendamustine, or clofarabine.
- If scheduled to receive combination regimens, the most emetogenic agent is to be given as first on Day 1 and the infusion must be completed within 6 hours.
- If scheduled to receive chemotherapy agents of minimal to low emetogenic potential, they are to be given on Day 1 following the most emetogenic agent 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 moderately emetogenic regimen based on laboratory criteria (Total Neutrophils,Platelets, Bilirubin, Liver enzymes, Serum Creatinine or Creatinine Clearance)

Exclusion Criteria:

- If female, lactating or pregnant
- Current use of illicit drugs or current evidence of alcohol abuse.
- Scheduled to receive either cyclophosphamide I.V. (500 to 1500 mg/m2) and I.V. doxorubicin (more or equal to 40 mg/m2) or cyclophosphamide I.V. (500 to 1500 mg/m2) and I.V. epirubicin (more or equal to 60 mg/m2).
- Scheduled to receive moderately or highly emetogenic chemotherapy from Day 2 to Day 5 following Day 1 chemotherapy administration.
- Active infection or uncontrolled disease except for malignancy that may pose unwarranted risks in administering the study drugs to the patient.
- Known hypersensitivity or contraindication to 5-HT3 receptor antagonists or dexamethasone.

- Previously received an NK1 receptor antagonist
- Participation in a clinical trial involving oral netupitant administered in combination with palonosetron.
- Any investigational drugs taken within 4 weeks prior to Day 1 of cycle 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 of cycle 1. Topical and inhaled corticosteroids with a steroid dose of less or equal to 10 mg of prednisone daily or its equivalent are permitted. Non-study drug dexamethasone as pre-medication in patients scheduled to receive taxanes is allowed.
- Scheduled to receive bone marrow transplantation and/or stem cell rescue therapy.
- Scheduled to receive any strong or moderate inhibitor of CYP3A4 or its intake within 1 week prior to Day 1
- Scheduled to receive any of the following CYP3A4 substrates: terfenadine, cisapride, astemizole, pimozide.
- Scheduled to receive any CYP3A4 inducer or its intake within 4 weeks prior to Day 1
- History or predisposition to cardiac conduction abnormalities, except for incomplete right bundle branch block.
- History of risk factors for Torsade de Point (heart failure, hypokalemia, family history of Long QT Syndrome).
- Severe cardiovascular diseases within 3 months prior to Day 1, including myocardial infarction, unstable angina pectoris, significant valvular or pericardial disease, history of ventricular tachycardia, symptomatic Congestive Heart Failure and severe uncontrolled arterial hypertension.
- Any illness or condition that, in the opinion of the investigator, may confound the results of the study or pose unwarranted risks in administering the investigational product to the patient.
- 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: Netupitant and Palonosetron plus dexamethasone Oral netupitant/palonosetron (300 mg/0.50 mg) hard capsule (on Day 1) with oral dexamethasone prior to each scheduled chemotherapy cycle	Drug: Netupitant and Palonosetron Drug: Dexamethasone
Active Comparator: Aprepitant and Palonosetron plus dexamethasone Oral aprepitant hard capsule 125 mg (on Day 1) + 80 mg daily (for the following two days) and oral palonosetron soft capsule 0.50 mg (on Day 1) given with oral dexamethasone at each scheduled chemotherapy cycle.	Drug: Aprepitant Drug: Palonosetron Drug: Dexamethasone

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Patients With Adverse Events	This was a safety study where Adverse Events is the primary outcome (defined by the current ICH Guideline for Good Clinical Practice). Patients were randomized according to a 3:1 ratio (netupitant/palonosetron:aprepitant/palonosetron). No formal comparison was planned, the presence of a control in the same patient population helped interpret any unexpected safety finding in the experimental arm.The number of patients was estimated in order to have more than 100 patients treated with the netupitant/palonosetron comination for up to at least six cycles. Based on 100 patients, if a given AE is not observed, an AE incidence of 3% or greater can be excluded with 95% confidence.	Participants will be followed for the duration of the chemotherapy, an expected average duration of up to 24 weeks assuming 6 chemotherapy cycles given every 4 weeks

Collaborators and Investigators

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

Sponsor

Helsinn Healthcare SA

Collaborators

- Parexel

Publications

From PubMed

These publications come from PubMed, a public database of scientific and medical articles. This list is automatically created by ClinicalTrials.gov Identifier (NCT Number), and these articles may or may not be about the study.

- Schwartzberg L, Karthaus M, Rossi G, Rizzi G, Borroni ME, Rugo HS, Jordan K, Hansen V. Fixed combination of oral NEPA (netupitant-palonosetron) for the prevention of acute and delayed chemotherapy-induced nausea and vomiting in patients receiving multiple cycles of chemotherapy: Efficacy data from 2 randomized, double-blind phase III studies. Cancer Med. 2019 May;8(5):2064-2073. doi: 10.1002/cam4.2091. Epub 2019 Apr 9. (https://pubmed.ncbi.nlm.nih.gov/30968588)

- Rugo HS, Rossi G, Rizzi G, Aapro M. Efficacy of NEPA (netupitant/palonosetron) across multiple cycles of chemotherapy in breast cancer patients: A subanalysis from two phase III trials. Breast. 2017 Jun;33:76-82. doi: 10.1016/j.breast.2017.02.017. Epub 2017 Mar 10. (https://pubmed.ncbi.nlm.nih.gov/28285236)

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

2011-06-16

HHS Vulnerability Disclosure

First Submitted that Met QC Criteria

2011-06-17

First Posted (Estimated)

2011-06-20

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)

2013-01-25

Study Record Updates

Last Update Submitted that met QC Criteria

2014-11-06

Last Update Posted (Estimated)

2014-11-17

Last Verified

2014-11

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
Neurokinin-1 Receptor Antagonists
Neurotransmitter Agents
Molecular Mechanisms of Pharmacological Action
Serotonin 5-HT3 Receptor Antagonists
Serotonin Antagonists
Serotonin Agents
Dexamethasone
Aprepitant
Palonosetron