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Completed

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

ClinicalTrials.gov ID NCT01339260

Sponsor Helsinn Healthcare SA

Information provided by Helsinn Healthcare SA (Responsible Party)

Last Update Posted 2014-11-26

Study Details Tab

Study Overview

Brief Summary

NETU-08-18 is a two-arm clinical study assessing efficacy and safety of a single oral dose of netupitant and palonosetron, two antiemetic drugs, versus oral palonosetron, both given with oral dexamethasone. The objective of the study is to demonstrate that netupitant and palonosetron are more effective than palonosetron alone, to prevent nausea and vomiting induced by moderately emetogenic cancer chemotherapy after administration of repeated cycles of chemotherapy.

Detailed Description

NETU-08-18 is a two-arm clinical study assessing efficacy and safety of a single oral dose of netupitant and palonosetron, two antiemetic drugs, versus oral palonosetron, both given with oral dexamethasone. Study is organised in two phases: cycle-1 and a multi-cycle extension. Safety assessment is performed separately in cycle 1 (arm 1 and arm 2) and in multi-cycle extension (arm 3 and arm 4).

Feedback

HELSINN EXHIBIT 2017
Azurity Pharmaceuticals, Inc. v. Helsinn Healthcare S.A.
IPR2025-00949

Official Title

A Phase III Multicenter, Randomized, Double-blind, Double-dummy, Active-controlled, Parallel Group Study of the Efficacy and Safety of Oral Netupitant Administered in Combination With Palonosetron and Dexamethasone Compared to Oral Palonosetron and Dexamethasone for the Prevention of Nausea and Vomiting in Cancer Patients Receiving Moderately Emetogenic Chemotherapy

Conditions

Chemotherapy-Induced Nausea and Vomiting

Intervention / Treatment

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

Other Study ID Numbers

Study Start

2011-04

Primary Completion (Actual)

2012-11

Enrollment (Actual)

1455

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 172 locations

United States

Alabama Locations

- **Anniston, Alabama, United States, 36207**
  Anniston Oncology/Regional Medical Center
- **Muscle Shoals, Alabama, United States, 35661**
  Northwest Alabama Cancer Center

Arkansas Locations

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

California Locations

- **Corona, California, United States, 92879**
  Compassionate Cancer Care Medical Group Inc
- **Fountain Valley, California, United States, 92708**
  Compassionate Cancer Centre Medical Group
- **Los Angeles, California, United States, 90017**

American Institute of Research

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

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

Whittier, California, United States, 90603
American Institute of Research

Colorado Locations

Denver, Colorado, United States, 80204
Denver Health and Hospital Authority

Florida Locations

Boynton Beach, Florida, United States, 33435
Palm Beach Institute of Hematology and Oncology

Jacksonville, Florida, United States, 32207
Baptist Cancer Institute

Indiana Locations

Evansville, Indiana, United States, 47713
Deaconess Clinic Downtown

New Albany, Indiana, United States, 47150
Floyd Memorial Cancer Center of Indiana

Kentucky Locations

Hazard, Kentucky, United States, 41701
Kentucky Cancer Clinic

Maryland Locations

Hagerstown, Maryland, United States, 21742
The John R Marsh Cancer Center

Massachusetts Locations

Worcester, Massachusetts, United States, 01608
Fallon Clinic at Worcester Medical Center

North Carolina Locations

Durham, North Carolina, United States, 27710
Duke University Medical Center

Winston-Salem, North Carolina, United States, 27103
Piedmont Hematology Oncology Associates PA

Ohio Locations

Massillon, Ohio, United States, 44646
Tri-County Hematology and Oncolgy Associates Inc.

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

South Carolina Locations

Charleston, South Carolina, United States, 29406
Charleston Cancer Center

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

Tennessee Locations

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

Texas Locations

Corpus Christi, Texas, United States, 78412
Cancer Specialists of South Texas, P.A.

Tyler, Texas, United States, 75708
The University of Texas Health Center

Utah Locations

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

Washington Locations

Tacoma, Washington, United States, 98405
Northwest Medical Specialties

Argentina

Cordoba, Argentina, X5006HBF
Instituto Oncológico de Córdoba - Sanatorio Aconcagua

Córdoba, Argentina, 5000
Hospital Italiano de Cordoba

Córdoba, Argentina, X5004FHP

Clínica Universitaria Reina Fabiola (Universidad Católica de Córdoba)

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

Mendoza, Argentina, M5500AYB
Centro Oncologico de Integracion Regional (COIR)

Quilmes, Argentina, B1878DVB
Instituto Médico CER [Oncology]

Rosario, Argentina, S2000DVS
Sanatorio Parque

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

Santa Fe, Argentina, 3000
ISIS Clinica Especializada

Belarus

Bobruisk, Belarus, 213825
Bobruisk Interregional Oncological Dispensary

Brest, Belarus, 224027
Brest Regional Oncological Dispensary

Brest, Belarus, 246012
Gomel Regional Clinical Oncological Dispensary

Minsk, Belarus, 220013
Minsk city Clinical Oncological Dispensary [Oncology]

Minsk, Belarus, 223040
State institution N.N. Alexandrov Republican Scientific and Practical Center of Oncology and Medical Radiology

Mogilev, Belarus, 212018
Mogilev Regional Oncological Dispensary [Oncology]

Brazil

Belo Horizonte, Brazil, 30150270
OXION-Medicina Oncológica

Cachoeiro de Itapemirim, Brazil, 29308-014
Centro de Pesquisas Clínicas em Oncologia

Caxias do Sul, Brazil, 95070-560
IPCEM - Centro de Ciências da Saúde - Universidade de Caxias

Goiânia, Brazil, 74605-070

Hospital Araújo Jorge

ItajaÃ, Brazil, 88301-220
Clinica de Neoplasias do Litoral

Porto Alegre, Brazil, 90430-090
Clinica De Oncologia De Porto Alegre S S Ltda

Porto Alegre, Brazil, RS90560-030
Hospital Moinhos de Vento

Ribeirão Preto, Brazil, 14015-130
Instituto Ribeirãopretano de Combate ao Cancer

Rio de Janeiro, Brazil, 22451010
Oncotrat Oncologia Medica Ltda [Oncology]

Salvador Bahia, Brazil, 40170-110
Nucleo de Oncologia da Bahia

São Paulo, Brazil, 04121-000
Hospital Santa Cruz

São Paulo, Brazil, 08270-070
Casa de Saude Santa Marcelina

Bulgaria

Blagoevgrad, Bulgaria, 2700
SHATO "Sveti Mina"

Gabrovo, Bulgaria, 5300
MHAT Dr. Tota Venkova [Oncology]

Haskovo, Bulgaria, 6300
Specialized Hospital for Active Treatment of Oncology

Pleven, Bulgaria, 5800
UMHAT ""Dr. Georgi Stranski"" Dept. Medical Oncology

Plovdiv, Bulgaria, 4002
UMHAT "Sveti Georgi" [Clinic of Oncology and Hematology]

Sofia, Bulgaria, 1233
District Dispensery with Stationary - Sofia District

Sofia, Bulgaria, 1527
UMHAT "Tsaritsa Yoanna - ISUL" Ltd.Medical Oncology Clinic

Sofia, Bulgaria, 1756
Specialized Hospital for Active Treatment in Oncology

Sofia, Bulgaria, 1784

Specialized Hospital for Active Treatment of Onclogy Diseases - Sofia City

Stara Zagora, Bulgaria, 6003
Complex Oncology Centre

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

Vratsa, Bulgaria, 3000
Comprehensive Cancer Center - Vratsa Dept. of Palliative Care

Croatia

Cakovec, Croatia, 40000
Županijska bolnica Cakovec

Osijek, Croatia, 31000
Klinicki bolnicki centar Osijek [Oncology]

Pula, Croatia, 52000
Opca bolnica Pula [Odjel za onklologiju]

Rijeka, Croatia, 51000
KBC Rijeka [Gastroenterology]

Varazdin, Croatia, 42 000
Opca bolnica Varazdin [Odjel za hem.onko i klin.imun.]

Zadar, Croatia, 23000
Opca Bolnica Zadal Ulica

Zagreb, Croatia, 10 000
Klinički bolnički centar Zagreb [Oncology]

Zagreb, Croatia, 10000
Klinicka bolnica [Sestre milosrdnice]

Zagreb, Croatia, 10000
Klinika za tumore [Odjel za kemoter. i internisticku onkolog

Germany

Berlin, Germany, 10117
Klinik und Poliklinik für Onkologie und Hämatologie Universitatsmedizin Charite Mitte

Berlin, Germany, 10317
Gynäkologische Arztpraxis

Hamburg, Germany, 22081
OncoResearch Lerchenfeld UG

Mannheim, Germany, 68161
Schwerpktprxs gynäkolog Onkologie Prof. Dr. Diel, Dr. Gebert

München, Germany, 80637
Rotkreuzklinikum [München]

München, Germany, 81545
Tumorzentrum Munchen Sued - Städtisches Klinikum [Hämato-, Onkologie + Palliativmed]

München, Germany, 81737
Staedtisches Krankenhaus Muenchen Neuperlach

Regensburg, Germany, 93053
OncoPRO GbR Dr. R. Dengler, Dr. A. Kröber Gesellschaft für klinische Studien in der ambulanten Hämatologie und Onkologie

Tübingen, Germany, 72076
Universitätsklinikum Tübingen

Velen, Germany, 46342
Praxis Dr. G. Dresemann

Weilheim, Germany, 82362
Onkologische Gemeinschaftspraxis Dr. med M. Perker / PF Dr. med M. Sandherr

Hungary

Budapest, Hungary, 1125
Semmelweis Egyetem Kútvölgyi Klinikai Tömb

Budapest, Hungary, 1145
Fővárosi Önkormányzat Uzsoki utcai Kórház

Győr, Hungary, 9024
Petz Aladár Megyei Oktató Kórház [Onkoradiológiai Oszt

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

Miskolc, Hungary, 3526
Borsod-Abaúj-Zemplén Megyei Kórház és Egyetemi Oktató Kórház

Nyíregyháza, Hungary, 4400
Josa Andras Oktato Korhaz [Onkologiai Osztaly]

Pécs, Hungary, 7624
Pécsi Tudományegyetem Klinikai Köpont

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

India

Ahmedabad, India, 380006
HCG - Multy Speciality Hospital

Ahmedabad, India, 380009
Hemato-Oncology Clinic Ahmedabad Pvt Ltd

Amravati, India, 444606
Sujan Surgical Cancer Hospital and Amracvati Cancer Foundation

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

Chennai, India, 600035
Apollo Speciality Hospital

Chennai, India, 600100
Dr. Kamahshi Memorial Hospital [Oncology]

Hyderabad, India, 500 024
BIBI General Hospital & Cancer Centre [Oncology]

Hyderabad, India, 500 082
Yashoda B-Block Hospital

Kolkata, India, 700053
B.P.Poddar Hospital and Medical Research Ltd

Kolkata, India, 700054
Apollo Gleneagles Hospitals Kolkata

Nashik, India, 422005
Shatabdhi Superspeciality Hospital

Pune, India, 411001
Grant Medical Foundation - Ruby Hall Clinic

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

Italy

Brescia, Italy, 25124
Fondazione Poliambulanza Istituto Ospedaliero

Lecce, Italy, 73100
Ospedale Vito Fazzi, ASL Lecce

Lecco, Italy, 23900
Presidio Ospedaliero "Alessandro Manzoni", AO Provincia di Lecco

Negrar, Italy, 37024
Ospedale Sacro Cuore e Don Calabria - Negrar

Potenza, Italy, 85100

Ospedale S.Carlo di Potenza [U.O. di Oncologia Medica]

Mexico

Chihuahua, Mexico, 31217
Centro Oncologico De Chihuahua

Mexico, Mexico, 06090
Hospital de Jesus

Mexico, Mexico, 20234
Centro Medico Quirurgico

Monterrey, Mexico, 64000
OCA Hospital/Monterrey International Research Center

Monterrey, Mexico, 64710
Centro Regiomontano de Investigación Clínica

Poland

Bialystok, Poland, 15-027
Bialostockie Centrum Onkologii im. M.Sklodowskiej-Curie

Elblag, Poland, 82-200
Wojewodzki Szpital Zespolony w Elblagu, Oddzial Onkologiczny

Koscierzyna, Poland, 83-400
Niepubliczny Specjalist. Onkol. Zaklad Opieki Zdrowotnej

Lodz, Poland, 93-513
Wojewodzki Szpital Specjalistyczny im. M.Kopernika

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

Olsztyn, Poland, 10-513
Olsztynski Osrodek Onkologiczny "KOPERNIK"

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

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" Baia-Mare [Oncologie Medicala]
- **Bucuresti, Romania, 011461**
  Spitalul Universitar de Urgenta Elias [Oncologie Medicala]
- **Bucuresti, Romania, 011464**
  Spitalul Clinic CF nr.2 Bucuresti [Oncologie Medicala]
- **Bucuresti, Romania, 050098**
  Spitalul Universitar de Urgenta Bucuresti
- **Bucuresti, Romania, 22328**
  Institutul Oncologic "Prof. Dr. Alex. Trestioreanu" [Sectia Clinica Radioterapie II]
- **Craiova, Romania, 200385**
  Oncolab - Oncology Center Craiova
- **Iasi, Romania, 700483**
  Institutul Regional de Oncologia
- **Onesti, Romania, 601048**
  Spitalul Municipal Onesti [Sectia Oncologie Medicala]
- **Tg Mures, Romania, 0540142**
  Spitalul Clinic Judetean Mures
- **Timisoara, Romania, 300239**
  Oncomed SRL

Russian Federation

- **Arkhangelsk, Russian Federation, 163045**
  GUZ Arkhangelsk Regional Clinical Oncological Dispensary
- **Ivanovo, Russian Federation, 153013**
  Ivanovo Regional Oncological Dispensary [Chemotherapy]
- **Kazan, Russian Federation, 420029**
  GAUZ Republic Clinical Oncology Dispensary of Ministry of Health of Republic Tatarstan
- **Krasnoyarsk, Russian Federation, 660133**
  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
Russian Cancer Research Center

Moscow, Russian Federation, 143423
SBHI of Moscow City Oncology Clinical Hospital #62

Novosibirsk, Russian Federation, 630047
MBUZ City Clinical Hospital #1

Obninsk, Russian Federation, 249036
FGBU Medical Radiology Scientific Center

Perm, Russian Federation, 614066
GUZ Perm Regional Oncology Dispensary

Pyatigorsk, Russian Federation, 357502
GUZ Pyatigorsk Oncology Dispensary [Outpatient Department]

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

Saint Petersburg, Russian Federation, 197022
City Oncology Dispensary

Saint Petersburg, Russian Federation, 197022
GOU VPO Saint-Petersburg State Medical University n.a. acad.

Saint Petersburg, Russian Federation, 197022
St. Petersburg Clinical Oncology Dispesary - 3rd Gynecology D

Saint-Petersburg, Russian Federation, 188663
GUZ "Leningrad Regional Oncology Dispensary"

Samara, Russian Federation, 443031
GUZ Samara Regional Clinical Oncology Dispensary

St. Petersburg, Russian Federation, 197758
FGU Research Institute of Oncology n.a. N.N.Petrov of Rosmed

Stavropol, Russian Federation, 355047
Stavropol Regional Clinical Oncology Dispensary

Ufa, Russian Federation, 450054
GBUZ - Clinical Oncology Dispensary of MoH of Republic Bahkortostan

Ufa, Russian Federation, 450054
GUZ Republican Clinical Oncological Dispensary of public

Ukraine

Cherkasy, Ukraine, 18009
Komunalnyi "Cherkaskyi oblasnyi onkolohichnyi dyspanser" Cherkaskoi oblasnoi rady, oblasnyi onkokhimioterapevtychnyi tsentr, m. Cherkasy

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

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

Dnipropetrovks, Ukraine, 49102
Komunalnyizaklad Miska bahatoprofilna klinichna likarnia #4

Donetsk, Ukraine, 83092
Donetskyi oblasnyi protypukhlynnyi tsentr

Kharkiv, Ukraine, 61070
Kharkivskyi oblasnyi onkologichnyi klinichnyi tsentr

Kyiv, Ukraine, 03115
Kyirskyi Miskyi klinichnyi onkolohichnyi tsentr

Kyiv, Ukraine, 04107
KZ KOR Kyivskyi oblasnyi onkologichnyi dyspanser

Lviv, Ukraine, 79031
Lvivskyi derzhavnyi onkologichnyi regionalnyi likuvalno diahnostychyi tsentr

Odessa, Ukraine, 65025
Odeska oblasna klinichna likarnia

Poltava, Ukraine, 36011
Poltavskyi oblasnyi klinichnyi onkolohichnyi dyspanser Pol

Uzhgorod, Ukraine, 88014
Zakarpatskyi oblasnyi klinichnyi onkodyspanser

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 will be permitted.
- Scheduled to receive first course of an anthracycline and cyclophosphamide containing moderately emetogenic chemotherapy (MEC) regimen for the treatment of a solid malignant tumor: 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).
- If scheduled to receive chemotherapy agents of minimal to low emetogenic potential they could be given on any day.
- Eastern Cooperative Oncology Group (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)

The following inclusion criteria must be checked prior inclusion at each cycle of the Multiple-Cycle Extension:

- Participation in the study during the next cycle of chemotherapy is considered appropriate by the investigator Satisfactory study compliance in the preceding cycle of chemotherapy and related study procedures.
- Scheduled to receive the same chemotherapy regimen as cycle 1
- Adequate hematologic and metabolic status as defined for cycle 1

Exclusion Criteria:

- If female, pregnant or lactating.
- Current use of illicit drugs or current evidence of alcohol abuse.
- Scheduled to receive any highly emetogenic chemotherapy (HEC) from Day 1 to Day 5 or moderately emetogenic chemotherapy (MEC) from Day 2 to Day 5 following the allowed MEC regimen.
- 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 in cycle 1.
- Any vomiting, retching, or mild nausea within 24 hours prior to Day 1.
- Symptomatic primary or metastatic central nervous system (CNS) malignancy.
- Active peptic ulcer disease, gastrointestinal obstruction, increased intracranial pressure, hypercalcemia, an active infection or any uncontrolled medical condition (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 or dexamethasone.
- Previously received a neurokin-1 (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.
- 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 of cycle 1
- Scheduled to receive any strong or moderate inhibitor of cytocrome P450 3A4 (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, including myocardial infarction within 3 months prior to Day 1, unstable angina pectoris, significant valvular or pericardial disease, history of ventricular tachycardia, symptomatic Congestive Heart Failure (CHF) New York Heart Association (NYHA) class III-IV, 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 such as systemic fungal infection or uncontrolled diabetes.

The following exclusion criteria must be checked prior inclusion at each cycle of the Multiple-Cycle Extension:

- If female, pregnant or lactating
- Active infection or uncontrolled disease except for malignancy.
- Started any of the restricted medications.
- Any vomiting, retching, or mild nausea 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: Netupitant and Palonosetron+dexamethasone-cycle 1 Oral netupitant/palonosetron (300 mg/0.50 mg) hard capsule with oral dexamethasone (12 mg), both given on Day 1, prior to each scheduled chemotherapy cycle	Drug: Netupitant and Palonosetron Drug: Dexamethasone
Active Comparator: Palonosetron+dexamethasone-cycle 1 Oral palonosetron 0.50 mg (Aloxi) with oral dexamethasone (20 mg) both given on Day 1, prior to each scheduled chemotherapy cycle	Drug: Palonosetron Drug: Dexamethasone
Experimental: Netupitant and Palonosetron+dexamethasone-multicycle extension Oral netupitant/palonosetron (300 mg/0.50 mg) hard capsule with oral dexamethasone (12 mg), both given on Day 1, prior to each scheduled chemotherapy cycle	Drug: Netupitant and Palonosetron Drug: Dexamethasone

Active Comparator: Palonosetron+dexamethasone-multicycle extension Oral palonosetron 0.50 mg (Aloxi) with oral dexamethasone (20 mg) both given on Day 1, prior to each scheduled chemotherapy cycle	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, at Cycle 1		25-120 hours

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Patients With Complete Response (CR) Defined as no		0-24 hours

Emesis, no Rescue Medication at Cycle 1		
Percentage of Patients With Complete Response (CR) Defined as no Emesis, no Rescue Medication, at Cycle 1		0-120 hours

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

2011-04-19

First Submitted that Met QC Criteria

2011-04-19

First Posted (Estimated)

2011-04-20

HHS Vulnerability Disclosure

Results Reporting Dates

Results First Submitted

2014-11-06

Results First Submitted that Met QC Criteria

2014-11-19

Results First Posted (Estimated)

2014-11-26

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

2014-11-19

Last Update Posted (Estimated)

2014-11-26

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

Dexamethasone

Palonosetron