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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

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/) (<https://medlineplus.gov/>) related topics: [Nausea and Vomiting](https://medlineplus.gov/nauseaandvomiting.html) (<https://medlineplus.gov/nauseaandvomiting.html>).

[Drug Information](https://dailymed.nlm.nih.gov/dailymed/) (<https://dailymed.nlm.nih.gov/dailymed/>) available for: [Dexamethasone](https://dailymed.nlm.nih.gov/dailymed/search.cfm?) (<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**

-  **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 Oncology 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**
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-  **Caxias do Sul, Brazil, 95070-560**
IPCEM - Centro de Ciências da Saúde - Universidade de Caxias
-  **Goiânia, Brazil, 74605-070**

Hospital Araújo Jorge

 Itajaí, 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

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 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, 6300Specialized 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 Dispensary 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
Oncology 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 onkologiju]

 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
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Germany

 Berlin, Germany, 10117

Klinik und Poliklinik für Onkologie und
Hämatologie Universitätsmedizin Charite Mitte

 Berlin, Germany, 10317

Gynäkologische Arztpraxis

 Hamburg, Germany, 22081

OncoResearch Lerchenfeld UG

 Mannheim, Germany, 68161

Schwerpktprxs gynäkolog Onkologie Prof. Dr.
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-  **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 Amravati
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 Medczone
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 Dispensary - 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 onkologichnyi 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 protypukhlynniy tsentr
- 📍 **Kharkiv, Ukraine, 61070**
Kharkivskyi oblasnyi onkologichnyi klinichnyi tsentr
- 📍 **Kyiv, Ukraine, 03115**
Kyirskyi Miskyi klinichnyi onkologichnyi tsentr
- 📍 **Kyiv, Ukraine, 04107**
KZ KOR Kyivskyi oblasnyi onkologichnyi dyspanser
- 📍 **Lviv, Ukraine, 79031**
Lvivskyi derzhavnyi onkologichnyi regionalnyi likuvalno diahnostychnyi tsentr
- 📍 **Odessa, Ukraine, 65025**
Odeska oblasna klinichna likarnia
- 📍 **Poltava, Ukraine, 36011**
Poltavskyi oblasnyi klinichnyi onkologichnyi 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) (<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 neurokinin-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 cytochrome 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 
<p>Experimental: Netupitant and Palonosetron+dexamethasone-cycle 1</p> <p>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</p>	<p>Drug: Netupitant and Palonosetron</p> <p>Drug: Dexamethasone</p>
<p>Active Comparator: Palonosetron+dexamethasone-cycle 1</p> <p>Oral palonosetron 0.50 mg (Aloxi) with oral dexamethasone (20 mg) both given on Day 1, prior to each scheduled chemotherapy cycle</p>	<p>Drug: Palonosetron</p> <p>Drug: Dexamethasone</p>
<p>Experimental: Netupitant and Palonosetron+dexamethasone-multicycle extension</p> <p>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</p>	<p>Drug: Netupitant and Palonosetron</p> <p>Drug: Dexamethasone</p>

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
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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, Apro 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