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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

**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/) (<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?labeltype=human&query=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) (<https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Dexamethasone+sodium+phosphate>) [Dexamethasone](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Dexamethasone)

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

[FDA Drug and Device Resources](https://clinicaltrials.gov/fda-links) (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) (https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations).

This study has 79 locations

### United States

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#### 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

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-  **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

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-  **Gabrovo, Bulgaria, 5300**  
MHAT Dr. Tota Venkova
-  **Sofia, Bulgaria, 1233**  
Specialized Hospital for Active Treatment 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

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-  **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


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-  **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

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-  **Budapest, Hungary, 1125**  
Szemmelweis Egyetem Kútvölgyi Klinikai Tömb
-  **Budapest, Hungary, 1145**  
Fővárosi Önkormányzat Uzsoki utcai Kórház
-  **Győr, 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


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 **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 Amravati  
Cancer Foundation


## Tamil Nadu Locations


 **Chennai, Tamil Nadu, India, 600035**  
Apollo Speciality Hospital


## Italy

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 **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.Carolo di Potenza

## Poland

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 **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. Kardynała S.  
Wyszynskiego
- Slupsk, Poland, 76-200**  
Wojewodzki Szpital Specjalistyczny im. J.  
Korczaka
- Warszawa, Poland, 02-781**  
Centrum Onkologii - Instytut im. Marii  
Skłodowskiej - Curie
- Warszawa, Poland, 04-125**  
NZOZ Magodent - Centrum Medczone  
Ostrobramska

## Romania





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- 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








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- 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 Dispensary

## Ukraine

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-  **Chernihiv, Ukraine, 14029**  
Komunalnyi likuvalno-profilaktychnyi zaklad  
"Chernigivskyi
-  **Dnipropetrovsk, Ukraine, 49102**  
Komunalnyi zaklad Miska bahatoprofilna  
klinichna likarnia #4
-  **Donetsk, Ukraine, 83092**  
Komunalno-klinichni likuvalno-profilaktychnyi  
zaklad
-  **Kharkiv, Ukraine, 61024**  
DU IMR AMNU [vd khemter]
-  **Kharkiv, Ukraine, 61070**  
Kharkivskyi oblasnyi onkologichni klinichni  
tsentr
-  **Khmelnyskyi, Ukraine, 29009**  
Chmelnyskyi 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 \(https://clinicaltrials.gov/study-basics/learn-about-studies\)](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/m<sup>2</sup> 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-HT<sub>3</sub> 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 ⓘ
<p>Experimental: Oral palonosetron plus dexamethasone</p> <p>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.</p>	<p>Drug: Oral palonosetron</p> <p>Drug: Dexamethasone</p>
<p>Active Comparator: I.V. palonosetron plus dexamethasone</p> <p>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.</p>	<p>Drug: I.V. palonosetron</p> <p>Drug: Dexamethasone</p>

## 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