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Completed

## An Efficacy and Safety Study of Intravenous Palonosetron Administered as an Infusion and as a Bolus for the Prevention of Nausea and Vomiting

ClinicalTrials.gov ID NCT02557035

Sponsor Helsinn Healthcare SA

Information provided by Helsinn Healthcare SA (Responsible Party)

Last Update Posted 2018-06-20

# Study Details Tab

### Study Overview

#### Brief Summary

PALO-15-17 is a clinical study assessing efficacy and safety of a single dose of palonosetron 0.25 mg administered as a 30-minute IV infusion compared to palonosetron 0.25 mg administered as a 30-second IV bolus (Aloxi, an antiemetic drug), both given with oral dexamethasone. The objective of the study is to demonstrate that infused IV palonosetron 0.25 mg is as effective as (non-inferior to) injected 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

A Phase 3, Single-dose, Multicenter, Randomized, Double-blind, Parallel Group Study to Assess the Efficacy and Safety of Palonosetron 0.25 mg Administered as a 30-minute IV Infusion Compared to

Feedback

Palonosetron 0.25 mg Administered as a 30-second IV Bolus for the Prevention of Chemotherapy-induced Nausea and Vomiting in Cancer Patients Receiving Highly Emetogenic Chemotherapy.

**Conditions** ⓘ

Chemotherapy-Induced Nausea and Vomiting

**Intervention / Treatment** ⓘ

- Drug: Palonosetron
- Drug: Dexamethasone

**Other Study ID Numbers** ⓘ**Study Start** ⓘ

2015-10

**Primary Completion (Actual)** ⓘ

2016-03

**Study Completion (Actual)** ⓘ

2016-03

**Enrollment (Actual)** ⓘ

441

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

[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) (<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 76 locations


### Belarus

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-  **Lesnoy, Belarus, 223052**  
N.N. Aleksandrov Republican Research  
Oncology and Medical Radiology Center,  
Department of Chemotherapy
-  **Minsk, Belarus, 220013**  
Minsk City Clinical Oncology Center

### Bosnia and Herzegovina

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-  **Banja Luka, Bosnia and Herzegovina**  
University Clinical Centre of the Republic of  
Srpska

### Bulgaria





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-  **Dobrich, Bulgaria, 9300**  
Multiprofile Hospital for Active Treatment,  
Dobrich, Department of Medical Oncology
-  **Haskovo, Bulgaria, 6300**  
Specialized Hospital for Active Treatment in  
Oncology, Haskovo, Department of Medical  
Oncology

-  **Plovdiv, Bulgaria, 4002**  
Multiprofile Hospital for Active Treatment  
"Central Onco Hospital", Plovdiv, Department of  
Medical Oncology
-  **Rousse, Bulgaria, 7002**  
Complex Oncology Center, Ruse, Department of  
Medical Oncology
-  **Sofia, Bulgaria, 1303**  
Multiprofile Hospital for Active Treatment  
"Serdika", Sofia, Department of Medical  
Oncology
-  **Sofia, Bulgaria, 1431**  
University Multiprofile Hospital for Active  
Treatment "Sveti Ivan Rilski", Sofia, Department  
of Medical Oncology
-  **Sofia, Bulgaria**  
Multiprofile Hospital for Active Treatment for  
Wonen's Health "Nadezhda"
-  **Varna, Bulgaria, 9010**  
Hospital for Active Treatment of Oncological  
Diseases "Dr. Marko Antonov Markov", Varna,  
Department of Medicinal Oncology and  
Palliative Care
-  **Varna, Bulgaria, 9010**  
Multiprofile Hospital for Active Treatment "Sveta  
Marina", Varna, Clinic of Medical Oncology



## Georgia


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-  **Tbilisi, Georgia, 0131**  
JSC NeoMedi
-  **Tbilisi, Georgia, 0159**  
LTD Institute of Clinical Oncology
-  **Tbilisi, Georgia, 0160**  
LTD Aversi Clinic
-  **Tbilisi, Georgia**  
LTD High Technology Medical Center University  
Clinic

## Greece

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-  **Athens, Greece**  
"Sotiria" Chest Diseases Hospital of Athens
-  **Thessaloniki, Greece, 570 01**  
Thermi Clinic S.A.


 **Thessaloniki, Greece, 570 10**  
General Hospital of Thessaloniki "G.  
Papanikolaou", University Department of  
Pulmonology


 **Thessaloniki, Greece**  
Bioclinic Thessalonikis S.A.


## Hungary


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 **Budapest, Hungary, 1121**  
Koranyi National Institute of TBC and  
Pulmonology


 **Budapest, Hungary, 1145**  
Uzsoki Hospital, Department of Radiation  
Oncology


 **Debrecen, Hungary**  
University of Debrecen, Medical and Health  
Science Center

 **Gyor, Hungary, 9024**  
Petz Aladar County Teaching Hospital, Center  
for Oncoradiology

 **Kaposvár, Hungary, 7400**  
Kaposi Mor Teaching Hospital, Centre for  
Clinical Oncology


 **Miskolc, Hungary, 3526**  
Borsod-Abauj-Zemplen County Hospital and  
University Educational Hospital


 **Nyíregyháza, Hungary**  
Szabolcs-Szatmar-Bereg County Hospitals and  
University Teaching Hospital

 **Pecs, Hungary**  
Medical Center of the University of Pecs

## Lithuania










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 **Kaunas, Lithuania, 45434**  
Hospital of Lithuanian University of Health  
Sciences Kaunas Clinics, Oncology Hospital,  
Department of Conservative Oncology

 **Kaunas, Lithuania, 50009**  
Hospital of Lithuanian University of Health  
Sciences Kaunas Clinics, Clinic of Oncology and  
Hematology

## Romania

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-  **Baia Mare, Romania**  
Oncopremium Team SRL, Department of  
Oncology
-  **Bucharest, Romania, 022328**  
Prof. Dr. Alexandru Trestioreanu Institute of  
Oncology, Medical Oncology Department II
-  **Bucharest, Romania, 030171**  
Coltea Clinical Hospital, Department of Medical  
Oncology
-  **Bucharest, Romania, 031864**  
Hifu Terramed Conformal SRL, Department of  
Medical Oncology
-  **Bucharest, Romania**  
Ianuli Med Consult SRL, Oncology Department
-  **Cluj-Napoca, Romania, 400015**  
"Prof. Dr. Ion Chiricuta" Institute of Oncology,  
Radiotherapy Department I
-  **Cluj-Napoca, Romania**  
Radiotherapy Center Cluj SRL, Department of  
Oncology
-  **Constanta, Romania, 900591**  
Constanta Emergency Clinical County Hospital,  
Department of Medical Oncology
-  **Craiova, Romania**  
Oncology Center "Sf. Nectarie", Department of  
Medical Oncology
-  **Suceava, Romania, 720237**  
Suceava Sf. Ioan cel Nou Emergency County  
Hospital, Department of Medical Oncology
-  **Timisoara, Romania, 300239**  
Oncomed SRL, Department of Medical Oncology
-  **Timisoara, Romania**  
Oncocenter Clinical Oncology SRL, Department  
of Medical Oncology













## Russian Federation

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-  **Arkhangelsk, Russian Federation**  
Arkhangelsk Clinical Oncology Center
-  **Barnaul, Russian Federation**  
Altay Territorial Oncology Center
-  **Bryansk, Russian Federation**  
Bryansk Regional Oncology Center
-  **Chelyabinsk, Russian Federation**

Chelyabinsk Regional Clinical Oncology Center

-  **Chelyabinsk, Russian Federation**  
Evimed, LLC
-  **Ekaterinburg, Russian Federation**  
Sverdlovsk Regional Oncology Center
-  **Ivanovo, Russian Federation**  
Ivanovo Regional Oncology Center
-  **Kaluga, Russian Federation**  
Kaluga Regional Oncology Center
-  **Kazan, Russian Federation**  
Republican Clinical Oncology Center
-  **Krasnoyarsk, Russian Federation**  
Krasnoyarsk A.I. Kryzhanovsky Regional  
Oncology Center
-  **Moscow, Russian Federation**  
Moscow City Oncology Hospital #62
-  **Moscow, Russian Federation**  
Moscow Clinical Scientific and Practical Center
-  **Moscow, Russian Federation**  
N.N. Blokhin Russian Oncology Research Center,  
Surgery Dept. 2
-  **Moscow, Russian Federation**  
N.N. Blokhin Russian Oncology Research Center,  
Surgery Dept. of Female Reproductive System  
Tumors
-  **Moscow, Russian Federation**  
N.N. Blokhin Russian Oncology Research Center
-  **Nizhny Novgorod, Russian Federation**  
Branch #1 of Nizhny Novgorod Regional  
Oncology Center
-  **Novosibirsk, Russian Federation**  
City Clinical Hospital #1
-  **Novosibirsk, Russian Federation**  
Novosibirsk Regional Oncology Center
-  **Omsk, Russian Federation**  
Clinical Oncology Center, Dept. of  
Chemotherapy
-  **Omsk, Russian Federation**  
Clinical Oncology Center
-  **Orenburg, Russian Federation**  
Orenburg Regional Clinical Oncology Center
-  **Pyatigorsk, Russian Federation**  
Pyatigorsk Oncology Center

-  **Ryazan, Russian Federation**  
Regional Clinical Oncology Center
-  **Samara, Russian Federation**  
Samara Regional Clinical Oncology Center
-  **St. Petersburg, Russian Federation**  
City Clinical Oncology Center, Thoracic  
Oncology Dept.
-  **St. Petersburg, Russian Federation**  
City Clinical Oncology Center, Urology Oncology  
Dept.
-  **St. Petersburg, Russian Federation**  
City Clinical Oncology Center
-  **St. Petersburg, Russian Federation**  
First I.P. Pavlov State Medical University of St.  
Petersburg
-  **St. Petersburg, Russian Federation**  
St.Petersburg Municipal Clinical Oncology  
Center
-  **Tambov, Russian Federation**  
Tambov Regional Oncology Center
-  **Tomsk, Russian Federation**  
Tomsk Research Institute of Oncology, General  
Oncology Dept.
-  **Tomsk, Russian Federation**  
Tomsk Research Institute of Oncology
-  **Ufa, Russian Federation**  
Republican Clinical Oncology Center
-  **Veliky Novgorod, Russian Federation**  
Regional Clinical Oncology Center

## 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
- Histologically or cytologically confirmed solid tumor malignancy.
- Naïve to cytotoxic chemotherapy. Previous biological or hormonal therapy will be permitted.
- Scheduled to receive first course of one of the following reference HEC, alone or in combination with other chemotherapeutic agents on Day 1:
  - cisplatin administered as a single IV dose of  $\geq 70$  mg/m<sup>2</sup>
  - cyclophosphamide  $\geq 1500$  mg/m<sup>2</sup>
  - carmustine (BCNU)  $>250$  mg/m<sup>2</sup>
  - dacarbazine (DTIC)
  - mechlorethamine (nitrogen mustard)
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2 .
- If a patient is female, she shall be of non-childbearing potential or of childbearing potential using reliable contraceptive measures and having a negative urine pregnancy test.
- Hematologic and metabolic status adequate for receiving an highly emetogenic regimen based on laboratory criteria (Total Neutrophils, Platelets, Bilirubin, Liver enzymes, Serum Creatinine or Creatinine Clearance)
- Able to read, understand, follow the study procedure and complete patient diary.

#### Exclusion Criteria:

- Lactating woman.
- Current use of illicit drugs or current evidence of alcohol abuse.
- Scheduled to receive moderately emetogenic chemotherapy or highly emetogenic chemotherapy from Day 2 to Day 5.
- Received or is scheduled to receive radiation therapy to the abdomen or the pelvis within 1 week prior to the start of the reference HEC administration on Day 1 or between Days 1 to 5.
- Any vomiting, retching, or nausea (grade  $\geq 1$  as defined by National Cancer Institute) within 24 hours prior to the start of the reference HEC administration on Day 1.
- Symptomatic primary or metastatic CNS malignancy.
- Active peptic ulcer disease, gastrointestinal obstruction, increased intracranial pressure, hypercalcemia, an active infection or any illness or 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) or pose unwarranted risks in administering the study drugs to the patient.
- Known hypersensitivity or contraindication to 5-HT<sub>3</sub> receptor antagonists
- Known contraindication to the IV administration of 50 mL 5% glucose solution.

- Participation in a previous 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 present study.
- Systemic corticosteroid therapy at any dose within 72 hours prior to the start of the reference HEC administration on Day 1. However, topical and inhaled corticosteroids 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 the start of the reference HEC administration on Day 1, including but not limited to 5-HT3 receptor antagonists and NK-1 receptor antagonists
- 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 ⓘ
<p>Experimental: I.V. palonosetron infusion plus dexamethasone</p> <p>Intravenous palonosetron (Aloxi 0.25 mg solution for injection) as an infusion 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: Palonosetron</p> <p>Drug: Dexamethasone</p>
<p>Active Comparator: I.V. palonosetron bolus plus dexamethasone</p> <p>Intravenous palonosetron (Aloxi 0.25 mg solution for injection) as a bolus 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: 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, in the Acute Phase		0-24 hours

### Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Percentage of Patients With Complete Response (CR) Defined as no Emesis, no Rescue Medication, in the Delayed Phase		>24-120 hours
Percentage of Patients With Complete		0-120 hours

Response (CR) Defined as no Emesis, no Rescue Medication, in the Overall Phase		
Percentage of Patients With no Emetic Episodes in the Acute Phase		0-24 hours
Percentage of Patients With no Emetic Episodes in the Delayed Phase		>24-120 hours
Percentage of Patients With no Emetic Episodes in the Overall Phase		0-120 hours
Percentage of Patients With no Rescue Medication in the Acute Phase		0-24 hours
Percentage of Patients With no Rescue Medication in		>24-120 hours

the Delayed Phase		
Percentage of Patients With no Rescue Medication in the Overall Phase		0-120 hours

## Collaborators and Investigators

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

### Sponsor ⓘ

**Helsinn Healthcare SA**

### Collaborators ⓘ

- PSI CRO

## 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 ⓘ

2015-09-21

#### First Submitted that Met QC Criteria ⓘ

2015-09-21

#### First Posted (Estimated) ⓘ

2015-09-22

## Results Reporting Dates

**Results First Submitted** ⓘ

2018-05-09

**Results First Submitted that Met QC Criteria** ⓘ

2018-06-18

**Results First Posted** ⓘ

2018-06-20

## Certification/Extension Dates

**Certification/Extension First Submitted** ⓘ

2016-03-23

**Certification/Extension First Submitted that Met QC Criteria** ⓘ

2016-03-23

**Certification/Extension First Posted (Estimated)** ⓘ

2016-04-26

## Study Record Updates

**Last Update Submitted that met QC Criteria** ⓘ

2018-06-18

**Last Update Posted** ⓘ

2018-06-20

**Last Verified** ⓘ

2018-06

## 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 [HHS Vulnerability Disclosure](#)

Serotonin 5-HT3 Receptor Antagonists

Serotonin Antagonists

Serotonin Agents

Neurotransmitter Agents

Molecular Mechanisms of Pharmacological Action

Dexamethasone

Palonosetron