A221301

Olanzapine for the Prevention of Chemotherapy Induced Nausea and Vomiting (CINV) in Patients Receiving Highly Emetogenic Chemotherapy (HEC): A Randomized, Double-Blind, Placebo-Controlled Trial

ClinicalTrial.gov Identifier: NCT02116530

Study Background

Trial Description

This randomized phase III trial studies antiemetic therapy with olanzapine to see how well they work compared to antiemetic therapy alone in preventing chemotherapy-induced nausea and vomiting in patients with cancer receiving highly emetogenic (causes vomiting) chemotherapy. Antiemetic drugs, such as palonosetron hydrochloride, ondansetron, and granisetron hydrochloride, may help lessen or prevent nausea and vomiting in patients treated with chemotherapy. Olanzapine may help prevent chemotherapy-induced nausea and vomiting by blocking brain receptors that appear to be involved in nausea and vomiting.

Arms:

Olanzapine + Chemotherapy + Antiemetic treatment: (Experimental): Patients will receive the chemotherapy drugs cisplatin or cyclophosphamide and doxorubicin as well as the following anti-nausea/vomiting drugs: Ondansetron (8 mg orally or intravenously) or granisetron (1 mg intravenously or 2 mg orally) or palonosetron (0.25 mg intravenously) on the day of chemotherapy, plus Dexamethasone (12 mg orally on the day of chemotherapy and 8 mg orally days 2, 3, 4 post chemotherapy), plus Fosaprepitant (150 mg intravenously on the day of chemotherapy) or aprepitant (125 mg orally on the day of chemotherapy and 80 mg orally on days 2 and 3 post chemotherapy), plus olanzapine (10 mg orally on the day of chemotherapy and 10 mg orally on days 2, 3, 4 post chemotherapy)

Placebo + Chemotherapy + Antiemetic treatment: (Active Comparator): Patients will receive the chemotherapy drugs cisplatin or cyclophosphamide and doxorubicin as well as usual anti-nausea/vomiting drugs: Ondansetron (8 mg orally or intravenously) or granisetron (1 mg intravenously or 2 mg orally) or palonosetron (0.25 mg intravenously) on the day of chemotherapy, plus Dexamethasone (12 mg orally on the day of chemotherapy and 8 mg orally days 2, 3, 4 post chemotherapy), plus Fosaprepitant (150 mg intravenously on the day of chemotherapy) or aprepitant (125 mg orally on the day of chemotherapy and 80 mg orally on days 2 and 3 post chemotherapy), plus placebo.

Objectives:

Patients with cancer may receive chemotherapy that may cause nausea and vomiting. The purpose of this study is to determine if the use of olanzapine in combination with antiemetic therapy can significantly reduce nausea and vomiting in a large number of patients receiving chemotherapy. Patients are randomized to one of two treatment arms. Please see the "Arms and Intervention" sections for more detailed information. The primary objective is to compare the number of patients with no nausea for the acute (0-24 hours post-chemotherapy), delayed (24-120 hours post-chemotherapy) and overall periods (0-120 hours post-chemotherapy) for patients receiving HEC. The secondary objectives are:

1. To compare the complete response (CR) (no emetic episodes and no use of rescue medication) in the acute, delayed and overall periods.
2. To compare the incidences of potential toxicities ascribed to olanzapine

Study Milestones:

Start date: August 2014

Primary Completion Date: April 2015

Publication Information:

Analysis Type: Primary

Pubmed ID: 27410922

Citation: N Engl J Med. 2016 Jul 14;375(2):134-42. doi: 10.1056/NEJMoa1515725.

Associated Datasets: NCT02116530-D1-Dataset.csv (master), NCT02116530-D2-Dataset.csv (aedat)

Dataset Information:

Dataset Name: NCT02116530-D2-Dataset.csv (aedat)

Description: Dataset NCT02116530-D2-Dataset.csv (aedat) is one of 2 datasets associated with PubMed ID 27410922. This dataset contains information on the adverse events reported in the publication.

Due to cleaning efforts subsequent to the publication, the data contains some minor discrepancies from those reported in the manuscript.

NCT02116530-D2-Dataset.csv (aedat) Data Dictionary:

LABEL	NAME	elements	comments
Patient Reference	PATREF		
Arm	ARM	Placebo, Olanzapine	
Cycle	CYCLE	2, 3, 4, 5	
Did patient have any adverse events?	ANYAE	No, Yes	ANYAE is a flag variable at the patient-level that indicates the patient reported any adverse event during any cycle. Sites were only required to submit Adverse Event details if the event was deemed grade 2 with an attribution of at least possibly related or the event was grade 3 or higher regardless of attribution. There were some patients that were flagged (ANYAE=YES) and were not required to submit details of the AE (a grade 1 or 2 that was not related or unlikely to be related to treatment).
Adverse event term (CTCAE v4.0)	toxicity		Missing indicates the patient did not report an adverse event for that cycle.
AE attribution	rel_smed	Definite, Possible, Unlikely, Probable, Unrelated	Missing indicates the patient did not report an adverse event that cycle.

Adverse event grade	grade	2, 1, 3, 4	Missing indicates the patient did not report an adverse event for that cycle.