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-D1-Dataset.csv (master)

Description: Dataset NCT02116530-D1-Dataset.csv (master) is one of 2 datasets associated with PubMed ID 27410922. This dataset contains information that will allow you to reproduce the baseline characteristics table and primary analysis.

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

Unless otherwise specified, missing values indicate the data was not reported.

NCT02116530-D1-Dataset.csv (master) Data Dictionary:

LABEL	NAME	elements	comments
Patient Reference	PATREF		
Arm	ARM	Placebo, Olanzapine	
Analysis Population	anly_pop	Evaluable for analysis:, Not evaluable for analysis: Withdrew, Not evaluable for analysis: Major Violations	
Evaluable for primary endpoint	priendpt_ok	Yes, No	
Age Group (Years)	age_grp	46 - 55, 66 - 75, 56 - 65, 76 and above, 35 and below, 36 - 45	Categories created to protect patient identity
Race or ethnic group	RACE1	American Indian or Alaska Native, Asian, Black or African American, Not assessed, White	
Gender	SEX	Female, Male	
5HT3 Receptor Antagonist	ANTRECPT	Palonosetron, Ondasetron, Granisetron	
Chemotherapy Regimen	CHEMOREG	Anthracycline and cyclophosphamide (AC), Cisplatin-containing regimen	
ECOG Performance Status	ECOGPS	0, 2, 1	

Primary site of disease	PRMSITEDZ	Breast, Lung, Other	
Acute Nausea	nausea_acute	Had Nausea, No Nausea	
Delayed Nausea	nausea_delayed	Had Nausea, No Nausea	
Overall Nausea	nausea_overall	Had Nausea, No Nausea	
Acute Response	acute_cr	No Response, Complete Response	
Delayed Response	delayed_cr	Complete Response, No Response	
Overall Response	overall_cr	No Response, Complete Response	
Day 1: Nausea (Worst nausea over the past 24 hours?)	NAUSEA_d1		Scale from 0 to 10. Where 0 is none and 10 is as bad as it can be.
Day 2: Nausea (Worst nausea over the past 24 hours?)	NAUSEA_d2		Scale from 0 to 10. Where 0 is none and 10 is as bad as it can be.
Day 3: Nausea (Worst nausea over the past 24 hours?)	NAUSEA_d3		Scale from 0 to 10. Where 0 is none and 10 is as bad as it can be.
Day 4: Nausea (Worst nausea over the past 24 hours?)	NAUSEA_d4		Scale from 0 to 10. Where 0 is none and 10 is as bad as it can be.
Day 5: Nausea (Worst nausea over the past 24 hours?)	NAUSEA_d5		Scale from 0 to 10. Where 0 is none and 10 is as bad as it can be.
Day 6: Nausea (Worst nausea over the past 24 hours?)	NAUSEA_d6		Scale from 0 to 10. Where 0 is none and 10 is as bad as it can be.
Day 1: Sedation Trouble (Undesired sedation trouble over the past 24 hours)	SEDATIONTRB_d1		Scale from 0 to 10. Where 0 is none and 10 is as bad as it can be.

Day 2: Sedation Trouble (Undesired sedation trouble over the past 24 hours)	SEDATIONTRB_d2		Scale from 0 to 10. Where 0 is none and 10 is as bad as it can be.
Day 3: Sedation Trouble (Undesired sedation trouble over the past 24 hours)	SEDATIONTRB_d3		Scale from 0 to 10. Where 0 is none and 10 is as bad as it can be.
Day 4: Sedation Trouble (Undesired sedation trouble over the past 24 hours)	SEDATIONTRB_d4		Scale from 0 to 10. Where 0 is none and 10 is as bad as it can be.
Day 5: Sedation Trouble (Undesired sedation trouble over the past 24 hours)	SEDATIONTRB_d5		Scale from 0 to 10. Where 0 is none and 10 is as bad as it can be.
Day 6: Sedation Trouble (Undesired sedation trouble over the past 24 hours)	SEDATIONTRB_d6		Scale from 0 to 10. Where 0 is none and 10 is as bad as it can be.
Day 1: Appetite Increase (Undesired appetite increase over the past 24 hours)	APPETITE_d1		Scale from 0 to 10. Where 0 is none and 10 is as bad as it can be.
Day 2: Appetite Increase (Undesired appetite increase over the past 24 hours)	APPETITE_d2		Scale from 0 to 10. Where 0 is none and 10 is as bad as it can be.
Day 3: Appetite	APPETITE_d3		Scale from 0 to

Increase (Undesired appetite increase over the past 24 hours)			10. Where 0 is none and 10 is as bad as it can be.
Day 4: Appetite Increase (Undesired appetite increase over the past 24 hours)	APPETITE_d4		Scale from 0 to 10. Where 0 is none and 10 is as bad as it can be.
Day 5: Appetite Increase (Undesired appetite increase over the past 24 hours)	APPETITE_d5		Scale from 0 to 10. Where 0 is none and 10 is as bad as it can be.
Day 6: Appetite Increase (Undesired appetite increase over the past 24 hours)	APPETITE_d6		Scale from 0 to 10. Where 0 is none and 10 is as bad as it can be.