A031201

Phase III Trial of Enzalutamide (NSC# 766085) Versus Enzalutamide, Abiraterone and Prednisone for Castration Resistant Metastatic Prostate Cancer

ClinicalTrials.gov Identifier: NCT01949337

Study Background

Trial Description

This randomized phase III trial studies enzalutamide to see how well it works compared to enzalutamide, abiraterone, and prednisone in treating patients with castration-resistant metastatic prostate cancer. Androgens can cause the growth of prostate cancer cells. Drugs, such as enzalutamide, abiraterone acetate, and prednisone, may lessen the amount of androgens made by the body.

Arms:

Arm A: (enzalutamide): (Experimental): Patients receive enzalutamide 160 mg PO QD. Treatment will continue until confirmed disease progression or unacceptable toxicity.

Arm B: (enzalutamide, abiraterone, prednisone): (Experimental): Patients receive enzalutamide 160 mg PO QD, abiraterone 1000 mg PO QD, and prednisone 5 mg PO BID. Treatment will continue until confirmed disease progression or unacceptable toxicity.

Objectives:

Patients are randomized to one of two treatment groups: enzalutamide or enzalutamide, abiraterone and prednisone. Treatment will continue until disease progression or unacceptable toxicity. Patients are followed for clinical outcomes for a maximum of 5 years post study treatment. The primary and secondary objectives are described below.

1. Primary Objective: To compare the overall survival of patients with progressive metastatic castration-resistant prostate cancer (CRPC) treated with either enzalutamide only or enzalutamide with abiraterone and prednisone
2. Secondary Objectives:
   - To assess the grade 3 or higher toxicity profile and compare safety by treatment arm.
   - To assess and compare post-treatment prostate-specific antigen (PSA) declines by treatment arm.
   - To compare radiographic progression free survival defined by Prostate Cancer Working Group 2 (PCWG2), and objective response rate, by treatment arm.

- To test for radiographic progression free survival (rPFS) treatment interaction in predicting overall survival.
- To assess pre- and post-treatment measures of tumor burden and bone activity using sodium fluoride (NaF) positron emission tomography (PET)/computed tomography (CT) and technetium (Tc) methylene diphosphonate (MDP) bone scintigraphy and correlate these measures with overall survival.
- To develop and validate prognostic and predictive models of overall survival that include baseline clinical and molecular markers.

Study Milestones:

Start date: January 22, 2014

Primary Completion Date: November 2, 2018

Publication Information:

Analysis Type: Primary

PubMed ID: 36996380

Citation: J Clin Oncol. 2023 Jun 20;41(18):3352-62. doi: 10.1200/JCO.22.02394. Epub 2023 Mar 30.

Associated Datasets: NCT01949337-D1-Dataset.csv (master), NCT01949337-D2-Dataset.csv (adverse_events), NCT01949337-D3-Dataset.csv (pk_abi), NCT01949337-D4-Dataset.csv (pk_enza)

Dataset Information:

Dataset Name: NCT01949337-D2-Dataset.csv (adverse_events)

Description: Dataset NCT01949337-D2-Dataset.csv (adverse_events) is one of 4 datasets associated with PubMed ID 36996380. This dataset contains data for adverse event analyses and tables.

Data can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases (e.g., when data must be modified for de-identification purposes or have undergone further data cleaning).

Blank values indicate data not applicable or missing, except where otherwise noted.

NCT01949337-D2-Dataset.csv (adverse_events) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient ID	id		
Arm	ARM	Enzalutamide, Enzalutamide+AAP	Treatment arm to which the patient was randomized.
All Grade Fatigue	allfatigue	No, Yes	
Grade 3+ Fatigue	gr3fatigue	No, Yes	
All Grade Acute Coronary Event	allace	No, Yes	
Grade 3+ Acute Coronary Event	gr3ace	No, Yes	
All Grade Atrial Fibrillation	allafib	No, Yes	
Grade 3+ Acute Atrial Fibrillation	gr3afib	No, Yes	
All Grade Hypertension	allhtn	No, Yes	
Grade 3+ Hypertension	gr3htn	No, Yes	
All Grade Arthralgia	allarthralgia	No, Yes	

LABEL	NAME	ELEMENTS	COMMENTS
Grade 3+ Arthralgia	gr3arthralgia	No, Yes	
All Grade Bone Pain	allbonepain	No, Yes	
Grade 3+ Bone Pain	gr3bonepain	No, Yes	
All Grade Anorexia	allanorexia	No, Yes	
Grade 3+ Anorexia	gr3anorexia	No, Yes	
All Grade AST/ALT increased	allastalt	No, Yes	
Grade 3+ ASL/ALT increased	gr3astalt	No, Yes	
All Grade Hypokalemia	allhypokalemia	No, Yes	
Grade 3+ Hypokalemia	gr3hypokalemia	No, Yes	
All Grade Edema	alledema	No, Yes	
Grade 3+ Edema	gr3edema	No, Yes	
All Grade Seizure	allseizure	No, Yes	
Grade 3+ Seizure	gr3seizure	No, Yes	
All Grade Nonheme Tox	allnonheme	No, Yes	
Grade 3+ Nonheme Tox	gr3nonheme	No, Yes	