CALGB-90202

A Randomized Double-Blind, Placebo-Controlled Phase III Study of Early Versus Standard Zoledronic Acid to Prevent Skeletal Related Events in Men With Prostate Cancer Metastatic to Bone

ClinicalTrial.gov Identifier: NCT00079001

Study Background

Trial Description

RATIONALE: Zoledronate may prevent or decrease skeletal (bone)-related events (such as pain or fractures) caused by bone metastases and androgen deprivation therapy. It is not yet known whether treatment with zoledronate is effective in preventing bone-related events in patients who have prostate cancer and bone metastases. PURPOSE: This randomized phase III trial is studying how well zoledronate works in preventing bone-related events in patients who are receiving androgen deprivation therapy for prostate cancer and bone metastases.

Arms:

Zoledronic acid + androgen deprivation therapy: (Experimental): 4mg by IV over 15 minutes every 4 weeks in the absence of disease progression or the first skeletal-related event. Participants who progress on blinded treatment before having a skeletal event may continue on open label Zoledronic acid (4 mg by IV over 15 minutes every 3 weeks).

Placebo + androgen deprivation therapy: (Active Comparator): Placebo by IV over 15 minutes for 4 weeks in the absence of disease progression or the first skeletal-related event. Participants who progress on blinded treatment before having a skeletal event may continue on open label Zoledronic acid.

Objectives:

- Zoledronic acid decreases the risk of skeletal related events in men with prostate cancer metastatic to bone and disease progression after primary hormonal therapy.
- This study is designed to evaluate whether earlier treatment with zoledronic acid will further decrease the risk of skeletal related events. This is a randomized, double-blind, placebo-controlled, multicenter study followed by an open-label study. Patients are stratified according to ECOG performance status (0-1 vs 2), prior skeletal-related event (no vs yes), and serum alkaline phosphatase (< upper limit of normal [ULN] vs ≥ ULN).

- The primary objective of the study is to determine whether treatment with zoledronic acid at the time of initiation of androgen deprivation therapy for metastatic prostate cancer will delay the time to first skeletal related event. The secondary objective of the study is to compare the effect of treatment with zoledronic acid to placebo on overall survival (OS),progression-free survival (PFS) and toxicity in men receiving androgen deprivation therapy for metastatic prostate cancer.
- Patients are randomized to 1 of 2 treatment arms. Treatment continues in the absence of disease progression or a skeletal-related event. All patients receive concurrent androgen deprivation therapy with a GnRH agonist. Patients also receive oral calcium and (vitamin D) supplements daily. Patients progressing to androgen-independent prostate cancer proceed to the open-label therapy with zoledronic acid IV. Treatment continues for 3 weeks in the absence of disease progression or the first skeletal-related event.
- Patients are followed periodically for approximately 10 years after entry on the study.

Study Milestones:

Start date: January 2004

Primary Completion Date: July 2012

Publication Information:

Analysis Type: Primary

Pubmed ID: 24590644

Citation: J Clin Oncol. 2014 Apr 10;32(11):1143-50. doi: 10.1200/JCO.2013.51.6500. Epub 2014 Mar 3.

Associated Datasets: NCT00079001-D1-Dataset.csv (baseline), NCT00079001-D2-Dataset.csv (analysis), NCT00079001-D3-Dataset.csv (ae)

Dataset Information:

Dataset Name: NCT00079001-D2-Dataset.csv (analysis)

Description: NCT00079001-D2-Dataset.csv (analysis) is one of 3 datasets associated with PubMed ID 24590644. This dataset contains information that will allow you to reproduce the primary analysis and time-to-event analysis.

NCT00079001-D2-Dataset.csv (analysis) Data Dictionary:

LABEL	NAME	elements	comments
PATIENT_ID	PATID		De-Identified patient reference
Treatment Assignment	TREAT_ASSIGNED	1 = Zoledronic acid 2 = Placebo	
Overall survival status	status	0 = Alive 1 = Dead	
Overall survival time in months	survival	Continuous	
Patient experienced SRE	SREflag	0 = No 1 = Yes	
Patient had progression or death	pfstatus	0 = No 1 = Yes	
Progression-free survival time in months	pftime	Continuous	
Months between registration and date of SRE	sretime	Continuous	
Discontinued Intervention Reason	offtrtstat	SRE ended treatment, Left to pursue alternative therapy, Death on treatment, Ended as a result of study termination	Missing means they continued treatment to completion