CALGB 40503:

Endocrine Therapy With or Without Anti-VEGF Therapy: A Randomized, Phase III Trial of Endocrine Therapy Alone or Endocrine Therapy Plus Bevacizumab (NSC 704865) for Women With Hormone Receptor-Positive Advanced Breast Cancer

ClinicalTrial.gov Identifier: NCT00601900

Study Background

Trial Design

This randomized phase III trial studies tamoxifen citrate or letrozole together with bevacizumab to see how well it works compared with tamoxifen citrate or letrozole alone in treating women with stage III or stage IV breast cancer. Estrogen can cause the growth of breast cancer cells. Hormone therapy using tamoxifen citrate or letrozole may fight breast cancer by blocking the use of estrogen by the tumor cells. Monoclonal antibodies, such as bevacizumab, may help control breast cancer by stopping the growth of blood vessels to the tumor. It is not yet known whether giving hormone therapy is more effective with or without bevacizumab in treating advanced breast cancer.

Arms:

- Experimental: Arm I (endocrine therapy with monoclonal antibody)
- Active Comparator: Arm II (endocrine therapy)

Objectives

Primary:

I. To compare the progression-free survival of letrozole therapy alone with the combination of letrozole therapy plus bevacizumab as first-line treatment in women with estrogen- and/or progesterone-receptor-positive advanced breast cancer.

Secondary:

I. Overall survival
II. Objective tumor response (measurable disease only)
III. Toxicity

Stratification Factors

Disease measurability:

1) No

2) Yes

Disease free interval (months from initial diagnosis to first progression)

3) $\leq$ 24 months
4) $>$ 24 months

Study History

Nov 2008 Activation as double-blinded placebo-controlled study

May 2010 Update #2, changed study from double-blinded to open label with the intent of increasing accrual.

June 2011 Phase II tamoxifen trial permanently closed.

Nov 2011 Phase III letrozole trial permanently closed.

May 2015 Efficacy/safety results of phase III trial presented at ASCO Annual Meeting

May 2016 Published online, JCO.

Publication Information

Analysis Type:

Primary Endpoint Analysis

PubMed ID:

27138575

Citation:

Dickler, M. N. et al. Phase III trial evaluating letrozole as first-line endocrine therapy with or without bevacizumab for the treatment of postmenopausal women with hormone receptor-positive advanced-stage breast cancer: CALGB 40503 (Alliance). J Clin Oncol. 34, 2602–2609, doi:10.1200/JCO.2015.66.1595 (2016).

Associated Datasets:
NCT00601900-D1 (efficacy)

NCT00601900-D2 (ae)

Dataset Information

Dataset Name: NCT00601900-D2 (ae)

Description:

This dataset contains information on adverse events. Contains one record per AE event per patient for those who began treatment.

Missing data indicates the information was not collected for that patient.

Variable description	Variable name	Codes	Notes
Identifier	patid		deidentified patient #
Adverse event number	aenum		AE number assigned to each adverse event that the patient experienced in chronological order (by the date the AE started).
Adverse event duration	aeduration		Number of days between the date the AE started and the date the AE ended.
was an AER submitted	AER_submitted	1=Yes 2=No	
AE meddra code	meddra_code		
version of CTC used	CTC_version		
version of meddra used	meddra_version		
grade of AE reported	grade_ID	0=none 1=mild 2=moderate 3=severe 4=life-threatening 5=fatal	
treatment attribution	relation_ID	1=definitely not related to rx 2=unlikely related to rx 3=possibly related to rx 4=probably related to rx 5=definitely related to rx	
AE name	eventname		
AE category	eventcat		
additional details of AE	select_AE		
Body system of the event	bodysys	Heme, Nonhematologic	