N0489

A Phase II Study of Epratuzumab, Rituximab (ER)-CHOP for Patients With Previously Untreated Diffuse Large B-Cell Lymphoma

ClinicalTrial.gov Identifier: NCT00301821

Study Background

Trial Description

RATIONALE: Monoclonal antibodies, such as epratuzumab and rituximab, can block cancer growth in different ways. Some block the ability of cancer cells to grow and spread. Others find cancer cells and help kill them or carry cancer-killing substances to them. Drugs used in chemotherapy, such as cyclophosphamide, doxorubicin, vincristine, and prednisone, work in different ways to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. Giving monoclonal antibody therapy together with chemotherapy may kill more cancer cells.

PURPOSE: This phase II trial is studying how well giving monoclonal antibody therapy together with combination chemotherapy works in treating patients with stage II, stage III, or stage IV diffuse large B-cell lymphoma.

Arms:

Epratuzumab + Rituximab + CHOP: (Experimental): One arm open label.

Objectives:

Primary

- Assess the efficacy of epratuzumab and rituximab in combination with cyclophosphamide, doxorubicin hydrochloride, vincristine, and prednisone (CHOP), as measured by 12-month, event-free survival, in patients with previously untreated stage II, III, or IV diffuse large B-cell lymphoma.
- Assess the use of positron emission tomography (PET) scan routinely early in treatment and after completion of treatment.
- Assess the functional response rate (complete response, partial response, or stable disease by CT scan and PET negative) in patients treated with this regimen.
- Assess the safety of this treatment regimen.

Publication Information:

Analysis Type: Primary

Pubmed ID: 21673350

Citation: Blood. 2011 Oct 13;118(15):4053-61. doi: 10.1182/blood-2011-02-336990. Epub 2011 Jun 14.

Associated Datasets: NCT00301821-D1-Dataset (outcome), NCT00301821-D2-Dataset (events)

Dataset Information:

Dataset Name: NCT00301821-D1-Dataset.csv (outcome)

Description: Dataset NCT00301821-D1-Dataset.csv (outcome) is one of 2 datasets associated with PubMed ID 21673350. This dataset contains information that will allow you to reproduce the baseline characteristics table, time-to-event analyses, and response analysis.

NCT00301821-D1-Dataset (outcome) Data Dictionary:

LABEL	NAME	elements	comments
Patient Reference	PATREF		Deidentified patient reference
ECOG PS	pscat	0, 1, 2 or 3	
B Symptoms Present	BSYMPTOM	No, Yes	
Follow-up Status	FU_STAT	Alive, Dead	
LDH Elevated	LDH_G	Yes, No	
Number of extranodal sites	NUMNODES	0, 1, >=2	
Gender	SEX	f, m	
Ann Arbor Stage	STAGE	3, 4, 2	
Eligible for final analysis	elig	0=no, 1=yes	
CD22 IHC	cd22	1=positive, 0=negative	Missing means the data was not collected
Pathology review status	path_ok	0=pathology ok, 1=pathology exclusion	Missing means the data was not collected
Bulky disease >10cm	bulky	0=No Bulky Disease, 1=Bulky Disease	
EFS status	EFS_stat	1=no event, 2=event	
PFS Status	PFS_stat	1=no PFS event, 2=PFS event	
Absolute lymphocyte counts (K/uL)	ALC	Continuous	Missing means the data was not collected
LDH (IU/L)	LDH	Continuous	Missing means the data was not collected
LDH UNL (IU/L)	LDH_UNL	Continuous	Missing means the data was not collected
EFS time in months	t_EFS_mth	Continuous	
OS time in months	t_fu_mth	Continuous	
PFS time in months	t_pfs_mth	Continuous	
PET status after 2 cycles	PET2	0=PET negative, 1=PET Positive	Missing means the data was not collected

PET status after 6 cycles	pet_post_trt	0=PET negative, 1=PET Positive	Missing means the data was not collected
Age Category	agecat	1=20<=agecat<40 2=40<=agecat<50 3=50<=agecat<60 4=60<=agecat<70 5=70<=agecat	
IPI category	ipicat	0 or 1, 2, 3, 4 or 5	
Cheson (CT) criteria after 2 cycles	resp_2	1=CR 1.5=CRu 2=PR 5=SD 19=N/A	
Cheson (CT) criteria after 6 cycles	resp_6	1=CR 1.5=CRu 2=PR 5=SD 19=N/A	
Age at registration (years)	AGE		