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COMPLETED ⓘ

High-Dose Sequential Therapy and Single Autologous Transplantation for Multiple Myeloma

ClinicalTrials.gov ID ⓘ NCT00349778

Sponsor ⓘ Stanford University

Information provided by ⓘ Sally Arai, Stanford University (Responsible Party)

Last Update Posted ⓘ 2017-12-12

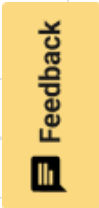
Table View Tab

Trial Contacts

Contacts	ICMJE
Contact information is only displayed when the study is recruiting subjects	

Study Record Dates

First Submitted	ICMJE
2006-07-05	
First Posted	ICMJE



2006-07-10

Results First Submitted

ICMJE

2017-04-26

Results First Posted

ICMJE

2017-12-12

Last Update Posted

2017-12-12

Last Verified

2017-11

Outcome Measures

Change History
[See all versions of this study.](#)
Primary (Current)

ICMJE

(Submitted: 2017-11-08)

- Number of Participants With Pulmonary Toxicity [Time Frame: 2 years]
 - Pulmonary toxicity was assessed as the incidence of interstitial pneumonitis.

Primary (Original)

ICMJE

(Submitted: 2006-07-05)

- Evaluate the risk of interstitial pneumonitis with the current dosing of BCNU and melphalan

Secondary (Current)

ICMJE

(Submitted: 2017-11-08)

- Overall Participant Survival (OS) [Time Frame: 5 years]
 - Survival status was assessed 5 years after transplant.
- Number of Participants That Relapse After Autologous Transplantation [Time Frame: 5 years]
 - Relapse was measured as the number of patients who relapse after high-dose sequential therapy then autologous transplantation

Secondary (Original)

ICMJE

(Submitted: 2006-07-05)

• Remission rate event free survival overall survival and relapse
Other Pre-specified (Current)
Not provided
Other Pre-specified (Original)
Not provided

Trial Description

Brief Title	ICMJE
High Dose Sequential Therapy and Single Autologous Transplantation for Multiple Myeloma	
Official Title	ICMJE
High-Dose Sequential Therapy and Single Autologous Transplantation for Multiple Myeloma	
Brief Summary	
This study uses a sequence of high dose chemotherapy drugs and a stem cell transplant to treat multiple myeloma The study is being performed to evaluate the efficacy and side effects of treatment Specifically the study is designed to reduce the risk of interstitial pneumonitis	
Detailed Description	
Analysis of 196 previously treated patients demonstrated a median event-free survival (EFS) of 36 months with a median overall survival of more than 6 years. The main toxicity of this therapy is related to carmustine induced pneumonitis or interstitial pneumonitis (IP) This complication is related to the dose of carmustine. Institutional experience in myeloma patients using this dose of carmustine indicates an incidence of IP of34%. There have been recent studies evaluating the role of tandem autologous transplants for patients with multiple myeloma. These trials were based upon the hypothesis that performing tandem high dose therapy regimens would lead to increased tumor cell kill decreased tumor burden and an improvement in overall survival. Our results with high-dose sequential therapy including the dose-intense carmustine/melphalan transplant demonstrates similar median EFS and overall survival (OS) when compared with the results of tandem transplant approaches The proposed trial will continue to use a high-dose sequential transplant approach, however, we will use a reduced dose of carmustine which we expect to be associated with a lower incidence of IP.	

Study Type

ICMJE

Interventional

Study Phase

ICMJE

Phase 2

Study Design

ICMJE

Allocation:

N/A

Interventional Model:

Single Group Assignment

Masking:

None (Open Label)

Primary Purpose

Treatment

Condition

ICMJE

- Multiple Myeloma

Intervention

ICMJE

- Drug: Cyclophosphamide
 - Cyclophosphamide as a white powder in 100 mg, 200 mg and 500 mg vials, to be dissolved in ~250 mL of saline or D5W and infused IV over 2 hours
 - Other Names:
 - Cytosan
 - Neosar
- Drug: Etoposide
 - 100 mg etoposide as 5 mL solution in clear ampules for injection.
 - Other Names:
 - Etopophos
 - VePesid
 - Toposar
 - VP-16
 - Etoposide phosphate
- Drug: Melphalan
 - Melphalan as single-use glass vials of freeze-dried melphalan hydrochloride (equivalent to 50 mg of melphalan), to be reconstituted in 0.9% sodium chloride solution to not

greater than 0.45 mg/mL, and administered within 1 hour of constitution.

- Other Names:
 - Alkeran
 - L-PAM
 - L-Sarcolysin
 - Phenylalanine mustard
- Drug: Carmustine
 - Carmustine as a powder for reconstitution in 100 mg vials, to be reconstituted with 3 mL sterile dehydrated ethanol and D5W. Carmustine should be dissolved in 500 mL of 5% dextrose in water (D5W) and infused IV over 2 hours.
 - Other Names:
 - BiCNU
 - BCNU
- Drug: Filgrastim
 - Filgrastim in vials of 300 µg or 480 µg at a concentration of 300 µg/mL, to be given as a daily subcutaneous injection.
 - Other Names:
 - Neupogen
 - Granulocyte-colony stimulating factor (G-CSF)

Study Arms

ICMJE

- Experimental: High-Dose Sequential Therapy
 - Cyclophosphamide + Etoposide + Melphalan + Carmustine with Filgrastim
 - Interventions:
 - Drug: Cyclophosphamide
 - Drug: Etoposide
 - Drug: Melphalan
 - Drug: Carmustine
 - Drug: Filgrastim

Publications *

- [Chen AI, Negrin RS, McMillan A, Shizuru JA, Johnston LJ, Lowsky R, Miklos DB, Arai S, Weng WK, Laport GG, Stockerl-Goldstein K. Tandem chemo-mobilization followed by high-dose melphalan and carmustine with single autologous hematopoietic cell transplantation for multiple myeloma. Bone Marrow Transplant 2012 Apr 47\(4\) 516 21 doi 10 1038/bmt 2011 106 Epub 2011 May 23.](https://pubmed.ncbi.nlm.nih.gov/21602899/) (https://pubmed.ncbi.nlm.nih.gov/21602899/)

* Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov identifier (NCT Number) in Medline.

Recruitment Information

Recruitment Status	ICMJE
Completed	
Enrollment (Actual) (Submitted: 2017-11-08)	ICMJE
102	
Original Enrollment (Submitted: 2006-07-05)	ICMJE
49	
Study Start Date	ICMJE
2006-08	
Primary Completion Date (Actual)	
2009 04 (Final data collection date for primary outcome measure)	
Study Completion Date (Actual)	ICMJE
2010-04	
Eligibility Criteria	ICMJE
INCLUSION CRITERIA	
• Stage II to III multiple myeloma or progression after initial treatment of Stage I disease early or relapsed • Age 18 to 75 years. • Pathology reviewed and the diagnosis confirmed at Stanford University Medical Center • Patients with amyloidosis may be eligible for this trial, with approval by the Principle Investigator. • Patients must have a Karnofsky performance status ≥ 70% • Aspartate aminotransferase (AST) must be < 2 x upper limit of normal (ULN) • Alanine aminotransferase (ALT) must be < 2 x ULN • Total bilirubin ≤ 2 mg/dL	

• Serum creatinine < 2.0 or 24-hour creatinine clearance ≥ 60 mL/min. • Patients must be HIV-negative. • Patients must provide signed, informed consent. EXCLUSION CRITERIA • Severe psychological or medical illness • Prior autologous hematopoietic cell transplantation • Pregnant • Lactating women • Smoldering multiple myeloma, • Monoclonal gammopathy of unknown significance or primary amyloidosis will be excluded from this study	
Sex/Gender	ICMJE
Sexes Eligible for the Study All	
Ages	ICMJE
18 Years to 75 Years (Adult, Older Adult)	
Accepts Healthy Volunteers	ICMJE
No	
Location Countries	ICMJE
United States	
Removed Location Countries	

Administrative Information

NCT Number	ICMJE
NCT00349778	
Other Study ID Numbers	ICMJE

IRB 05704

97115(Other Identifier)

BMT183(Other Identifier)

Has Data Monitoring Committee

Yes

U.S. FDA-regulated Product

Studies a U.S. FDA-regulated Drug Product:

Yes

Studies a U.S. FDA-regulated Device Product:

No

Product manufactured in and exported from the U.S:

No

IPD Sharing Statement[ICMJE](#)

Plan to Share IPD:

No

Current Responsible Party

Sally Arai, Stanford University

Original Responsible Party[Not provided](#)**Current Study Sponsor**[ICMJE](#)

Stanford University

Original Study Sponsor[ICMJE](#)[Same as current](#)**Collaborators**[ICMJE](#)

Not provided

Investigators[ICMJE](#)

Principal Investigator:

Sally Arai

Stanford University

PRS Account
Stanford University

CMJE Data element required by the [International Committee of Medical Journal Editors](#) and the [World Health Organization ICTRP](#)