Informe de respuesta rápida

Solicitado por: Dra. Olga Peña, Dr. Francisco Vallejo
Fecha de la solicitud (dd/mm/aaaa): 27/08/2012

Pregunta general:

Opciones de tratamiento para amiloidosis hepática.

Ámbito de la pregunta ☑

☑ Tratamiento o prevención	☐ Guías de predicción clínica
☐ Diagnóstico	☑ Guías de práctica clínica
☐ Pronostico	☐ Eficiencia (Costos)
☐ Etiología	☐ Definición de políticas

Términos utilizados

Población/problema	*Exposición*	*Comparación*	*Resultados*
Amiloidosis hepática	Tratamiento	---	Eficacia

Estrategia de búsqueda:

1. "Amyloidosis"[Mesh] Filters: Practice Guideline
2. amiloidosis (texto libre)

Tipo de estudios ☑

☑ Guías de Práctica Clínica	☑ Series de caso

Fuentes de datos consultadas ☑

☑ PubMed / MEDLINE ☑ MD Consult ☑ EBSCO DynaMed	☑ Repositorios de Guías (NGC, NeLH) ☑ BMJ Best Practice

☑ Otras: Portales de sociedades científicas relacionadas con el manejo de amiloidosis o mieloma múltiple.

Resultados de la búsqueda

Documentos selecionados: 10

Recomendaciones y nivel de evidencia (GRADE):	Nivel (Alto, Moderado, Bajo, Muy bajo)	Fuerza de recomendación (Fuerte, Débil)
En pacientes con amiloidosis AL que no son candidatos para terapia de remplazo autólogo con células madre se sugiere considerar el uso de melfalán asociado a dexametasona en altas dosis en lugar de la asociación melfalán más prednisona.	Bajo	Fuerte
El trasplante hepático no debe considerarse como una opción de primera línea para el tratamiento de amiloidosis AL.	Bajo	Fuerte

Resumen

La amiloidosis sistémica primaria ocurre en alrededor del 8 por millón de personas por año. La edad media al momento del diagnóstico es de 64 años, pero se puede presentar a cualquier edad. La relación hombre-mujer es de casi 2:1.

Todas las estrategias actuales de manejo incluyen la destrucción de las células plasmáticas responsables de la síntesis de cadena ligera de inmunoglobulina. El objetivo de la terapia incluye la eliminación de las cadenas proteicas ligeras con plegamiento erróneo lo más pronto posible para evitar su toxicidad y el tratamiento de soporte para el o los órganos afectados.

El tratamiento de elección es melfalán en altas dosis más trasplante autólogo de células madre (SCT). Sin embargo este tratamiento no está indicado en pacientes con alguno de los siguientes criterios:

Contraindicaciones absolutas:
- Insuficiencia cardíaca congestiva
- Bilirrubina total >3.0 mg/dL
- Fracción de eyección evaluada por ecocardiografía <30%

Contraindicaciones relativas:
- Creatinina sérica < 2.0 mg/dL
- Engrosamiento del tabique interventricular <15mm
- Edad >60 años
- Más de dos órganos involucrados

En pacientes con amiloidosis AL que no son candidatos para terapia de remplazo autólogo con células madre se sugiere considerar el uso de melfalán asociado a dexametasona en altas dosis en lugar de la asociación melfalán más prednisona. La combinación de melfalán y dexametasona tiene el historial más largo con resultados de 5 años de seguimiento y es considerado como la principal opción para el tratamiento de terapia pacientes con amiloidosis AL que no son candidatos para terapia de remplazo autólogo con células madre. Algunos estudios no encontraron diferencias significativas en la sobrevida y tasas de remisión entre melfalán+SCT versus melfalán+dexametasona.(1-5)

Para evaluar la respuesta al tratamiento se pueden realizar estudios de inmunoglobulina de cadena ligera libre y determinar la duración de la terapia (normalmente entre 6 a 12 meses).

Las opciones secundarias de tratamiento incluyen ciclofosfamida, dexametasona y talidomida (CDT), o lenalidomida y dexametasona. Se pueden considerar las siguientes asociaciones:

- bortezomib ± dexametasona
- bortezomib + mephalan + dexametasona
- dexametasona + interferón alfa
- ciclofosfamida + talidomida + dexametasona
- lenalidomida + dexametasona
- talidomida + dexametasona
- bortezomib + ciclofosfamida + dexametasona

La dexametasona como fármaco único se puede considerar en pacientes considerados demasiado frágiles para terapia con melfalán, pero las tasas de respuesta parecen ser más bajas.(6)

En casos de respuesta incompleta al primer ciclo de quimioterapia, se puede considerar la terapia con bortezomib o la inscripción del paciente en un ensayo clínico. En casos de recaída después del tratamiento se pueden repetir cursos mensuales de melfalán y dexametasona, ciclofosfamida durante 6 a 12 meses, dexametasona y talidomida (CDT), la lenalidomida con dexametasona mensual por tiempo indefinido, o bortezomib y dexametasona.

La colchicina es eficaz únicamente en la amiloidosis asociada con la fiebre mediterránea familiar y no debe utilizarse en el tratamiento de amiloidosis primaria AL.(7,8)

Si bien se han reportado casos anecdóticos de trasplante hepático para el tratamiento de pacientes con amiloidosis AL, éste no remplaza al tratamiento quimioterapéutico necesario para la supresión de las células plasmáticas productoras de inmunoglobulinas de cadena corta y se debe reservar como una opción de manejo sólo en los casos de amiloidosis de la forma transtiretina, en los que el trasplante de hígado es la única intervención conocida para estabilizar la enfermedad.(9)

El pronóstico para los pacientes con amiloidosis primaria AL (es decir, cadena ligera de inmunoglobulina) después del tratamiento es dependiente del impacto de la terapia en la supresión de la síntesis de inmunoglobulina de cadena ligera. En los pacientes que alcanzan una respuesta completa al tratamiento, la supervivencia a los 7 años se aproxima al 80%. Para los pacientes que logran una reducción del 50% en el tratamiento a los 7 años, la supervivencia es del 57%. Para los pacientes que no han podido demostrar una respuesta con el uso de terapias de rescate apropiadas, la supervivencia es del 30%.(10)

Responsables:	*Revisado por:*	*Fecha de elaboración:*
Dr. Rodrigo Henríquez	Econ. Ruth Lucio	28/08/2012

Anexo 1. Citas bibliográficas de los documentos seleccionados

1. National Comprehensive Cancer Network (NCCN). NCCN Guidelines versión 1.2013. Systemic Light Chain Amyloidosis. Disponible en: http://www.nccn.org/professionals/physician_gls/pdf/amyloidosis.pdf

2. Palladini G, Russo P, Nuvolone M, et al. Treatment with oral melphalan plus dexamethasone produces long-term remissions in AL amyloidosis. Blood 2007;110:787–8.
3. Palladini G, Perfetti V, Obici L, et al. Association of melphalan and high-dose dexamethasone is effective and well tolerated in patients with AL (primary) amyloidosis who are ineligible for stem cell transplantation. Blood 2004;103:2936–8.
4. Jaccard A, Moreau P, Leblond V, et al. High-dose melphalan versus melphalan plus dexamethasone for AL amyloidosis. The New England journal of medicine 2007;357:1083–93.
5. Jaccard A, Leblond V, Royer B, et al. Autologous Stem Cell Transplantation (ASCT) Versus Oral Melphalan and High-Dose Dexamethasone In Patients with AL (Primary) Amyloidosis: Long Term Follow-up of the French Multicentric Randomized Trial. ASH Annual Meeting Abstracts 2010;116:1344.
6. Gertz MA, Lacy MQ, Lust JA, et al. Phase II trial of high-dose dexamethasone for untreated patients with primary systemic amyloidosis. Med Oncol. 1999;16:104-109.
7. Guidelines on the diagnosis and management of AL amyloidosis. British journal of haematology 2004;125:681–700.
8. Lidar M, Livneh A. Familial Mediterranean fever: clinical, molecular and management advancements. Neth J Med. 2007;65:318-324.
9. Zhang KY, Tung BY, Kowdley KV. Liver transplantation for metabolic liver diseases. Clin Liver Dis. 2007;11:265-281.
10. Gertz MA, Lacy MQ, Dispenzieri A, et al. Effect of hematologic response on outcome of patients undergoing transplantation for primary amyloidosis: importance of achieving a complete response. Haematologica. 2007;92:1415-1418.

Anexo 2. Listado de ensayos clínicos controlados en fase de reclutamiento que podrían beneficiar a personas con amiloidosis.

Fuente: http://www.clinicaltrials.gov
Fecha de consulta: 28/08/2012

Study 1:
NCT Number: NCT00651937
Title: Trial of Two Stem Cell Doses To Reduce Transplant Induced Symptom Burden
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Multiple Myeloma|Primary Amyloidosis
Interventions: Drug: Melphalan|Procedure: Stem Cell Infusion|Behavioral: Questionnaires|Drug: Granulocyte-colony stimulating factor (G-CSF)|Procedure: Apheresis
Sponsor/Collaborators: M.D. Anderson Cancer Center|M.D. Anderson Cancer Center
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 100
Funded Bys: Other
Study Types: Interventional
Study Designs: Allocation: Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Masking: Open Label|Primary Purpose: Treatment
Other IDs: 2005-0601
First Received: March 31, 2008
Start Date: March 2008
Completion Date:
Last Updated: August 20, 2012
Last Verified: August 2012
Acronym:
Primary Completion Date: March 2016
Outcome Measures: Mean Symptom Severity Score|Number of patients receiving a higher stem cell dose who have a lower increase in mean symptom severity score at one week after infusion of high dose chemotherapy as compared to patients receiving the lower stem cell dose
URL: http://ClinicalTrials.gov/show/NCT00651937

Study 2:
NCT Number: NCT00890552
Title: A Pilot Study of Lenalidomide, Melphalan and Dexamethasone in AL Amyloidosis
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Leukemia|Amyloidosis
Interventions: Drug: Lenalidomide|Drug: Melphalan|Drug: Dexamethasone
Sponsor/Collaborators: Stanford University|Stanford University|Celgene Corporation
Gender: Both
Age Groups: Adult|Senior
Phases:
Enrollment: 15
Funded Bys: Other|Industry
Study Types: Interventional
Study Designs: Allocation: Non-Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Single Group Assignment|Masking: Open Label|Primary Purpose: Treatment
Other IDs: HEM0010|RV-AMYL-PI-0375|SU-09192008-1300
First Received: April 28, 2009
Start Date: April 2009
Completion Date:
Last Updated: May 10, 2012
Last Verified: May 2012
Acronym:
Primary Completion Date: December 2012
Outcome Measures: Safety and tolerability of Intervention|Hematologic and organ responses, time to progression
URL: http://ClinicalTrials.gov/show/NCT00890552

Study 3:
NCT Number: NCT00681044
Title: High-Dose Melphalan and Stem Cell Transplant in Treating Patients With Immunoglobulin Deposition Disease or Light-Chain Deposition Disease
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Multiple Myeloma and Plasma Cell Neoplasm
Interventions: Biological: filgrastim|Drug: melphalan|Procedure: autologous hematopoietic stem cell transplantation
Sponsor/Collaborators: Boston Medical Center|Boston Medical Center
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 30
Funded Bys: Other
Study Types: Interventional
Study Designs: Intervention Model: Single Group Assignment|Masking: Open Label|Primary Purpose: Treatment
Other IDs: CDR0000595782|BHO-H-25876|BUMC-H-25876
First Received: May 18, 2008
Start Date: October 2006
Completion Date: February 2030
Last Updated: February 27, 2012
Last Verified: February 2012
Acronym:
Primary Completion Date: October 2014
Outcome Measures: Tolerability|Hematologic response rate|Predictability of early free light-chain response for heme response|Organ or clinical response|Overall survival
URL: http://ClinicalTrials.gov/show/NCT00681044

Study 4:
NCT Number: NCT01083316
Title: Bortezomib and Dexamethasone Followed by High-Dose Melphalan and Stem Cell Transplantation for Primary (AL) Amyloidosis
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Amyloidosis

Interventions: Drug: Bortezomib (Velcade) and Dexamethasone
Sponsor/Collaborators: Boston Medical Center|Boston Medical Center|Millennium Pharmaceuticals, Inc.
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 30
Funded Bys: Other|Industry
Study Types: Interventional
Study Designs: Allocation: Non-Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Single Group Assignment|Masking: Open Label|Primary Purpose: Treatment
Other IDs: H-28441|X05292
First Received: November 2, 2009
Start Date: September 2009
Completion Date: December 2040
Last Updated: January 9, 2012
Last Verified: June 2011
Acronym:
Primary Completion Date: December 2013
Outcome Measures: Disease Response|To determine overall survival|To assess safety
URL: http://ClinicalTrials.gov/show/NCT01083316

Study 5:
NCT Number: NCT00679367
Title: Melphalan, Lenalidomide, and Dexamethasone in Treating Patients With Primary Systemic Amyloidosis
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Multiple Myeloma and Plasma Cell Neoplasm
Interventions: Drug: dexamethasone|Drug: lenalidomide|Drug: melphalan
Sponsor/Collaborators: Boston Medical Center|Boston Medical Center
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 35
Funded Bys: Other
Study Types: Interventional
Study Designs: Intervention Model: Single Group Assignment|Masking: Open Label|Primary Purpose: Treatment
Other IDs: CDR0000595759|BHO-H-26320|BHO-RV0219|BUMC-H-26320
First Received: May 14, 2008
Start Date: May 2008
Completion Date: May 2030
Last Updated: February 27, 2012
Last Verified: February 2012
Acronym:
Primary Completion Date: May 2013
Outcome Measures: Hematologic response rate as measured by standard criteria|Safety (i.e., type, frequency, severity, and relationship of adverse events to study treatment)|Organ response
URL: http://ClinicalTrials.gov/show/NCT00679367

Study 6:
NCT Number: NCT01277016
Title: A Trial for Systemic Light-chain (AL) Amyloidosis
Recruitment: Recruiting
Study Results: No Results Available
Conditions: AL Amyloidosis
Interventions: Drug: BMDex
Sponsor/Collaborators: European Myeloma Network|European Myeloma Network
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 3
Enrollment: 110
Funded Bys: Other
Study Types: Interventional
Study Designs: Allocation: Randomized|Endpoint Classification: Efficacy Study|Intervention Model: Parallel Assignment|Masking: Open Label|Primary Purpose: Treatment
Other IDs: EMN-03|2010-022395-31
First Received: January 10, 2011
Start Date: January 2011
Completion Date: January 2013
Last Updated: September 2, 2011
Last Verified: January 2011
Acronym: EMN-03
Primary Completion Date: July 2012
Outcome Measures: Number of Patients in CR and PR measured by level of serum light chain monoclonal protein|Compare haematology response
URL: http://ClinicalTrials.gov/show/NCT01277016

Study 7:
NCT Number: NCT01383759
Title: Bortezomib/Dexamethasone (BD), Followed By Autologous Stem Cell Transplantation and Maintenance Bortezomib/Dexamethasone For the Initial Treatment of Monoclonal Immunoglobulin Deposition Disease (MIDD) Associated With Multiple Myeloma and AL Amyloidosis
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Light Chain Deposition Disease (LCDD or MIDD)|Light Chain and Heavy Chain Deposition Disease (LHCDD or MIDD)|Monoclonal Immunoglobulin Deposition Disease (MIDD)|Amyloidosis
Interventions: Drug: Bortezomib/Dexamethasone (BD), Followed By Autologous STC & Maintenance Bortezomib/Dexamethasone
Sponsor/Collaborators: Memorial Sloan-Kettering Cancer Center|Memorial Sloan-Kettering Cancer Center|Millennium Pharmaceuticals, Inc.
Gender: Both
Age Groups: Adult|Senior
Phases:
Enrollment: 35
Funded Bys: Other|Industry
Study Types: Interventional
Study Designs: Allocation: Non-Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Single Group Assignment|Masking: Open Label|Primary Purpose: Treatment
Other IDs: 11-061
First Received: June 27, 2011
Start Date: June 2011
Completion Date: June 2013
Last Updated: May 8, 2012
Last Verified: May 2012
Acronym:
Primary Completion Date: June 2013
Outcome Measures: To examine the tolerability|To examine the toxicity|To estimate the hematologic response rate|To estimate the organ response rate at the end of treatment|To estimate the time to hematologic progression
URL: http://ClinicalTrials.gov/show/NCT01383759

Study 8:

NCT Number: NCT01510613
Title: Pomalidomide and Dexamethasone (PDex) in AL Amyloidosis
Recruitment: Not yet recruiting
Study Results: No Results Available
Conditions: Primary Amyloidosis of Light Chain Type
Interventions: Drug: Pomalidomide and Dexamethasone
Sponsor/Collaborators: IRCCS Policlinico S. Matteo|IRCCS Policlinico S. Matteo
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 28
Funded Bys: Other
Study Types: Interventional
Study Designs: Intervention Model: Single Group Assignment|Masking: Open Label|Primary Purpose: Treatment
Other IDs: AC-007-IT|2011-001787-22
First Received: January 11, 2012
Start Date: February 2012
Completion Date:
Last Updated: January 13, 2012
Last Verified: January 2012
Acronym:
Primary Completion Date: February 2013
Outcome Measures: Efficacy of PDex|Safety of PDex
URL: http://ClinicalTrials.gov/show/NCT01510613

Study 9:
NCT Number: NCT01570387
Title: A Phase I/II Trial of Pomalidomide and Dexamethasone in Subjects With Previously-Treated AL Amyloidosis
Recruitment: Recruiting
Study Results: No Results Available
Conditions: AL Amyloidosis
Interventions: Drug: Pomalidomide|Drug: Dexamthasone
Sponsor/Collaborators: Boston Medical Center|Boston Medical Center|Celgene Corporation
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 1|Phase 2
Enrollment: 35
Funded Bys: Other|Industry
Study Types: Interventional
Study Designs: Endpoint Classification: Safety/Efficacy Study|Intervention Model: Single Group Assignment|Masking: Open Label|Primary Purpose: Treatment
Other IDs: H-31082|PO-AMYL-PI-0024
First Received: February 27, 2012
Start Date: June 2012
Completion Date: February 2030
Last Updated: July 6, 2012
Last Verified: June 2012
Acronym:
Primary Completion Date: February 2015
Outcome Measures: Determining dose-limiting toxicity and maximal tolerated dosage|Response to the maximal tolerated dose
URL: http://ClinicalTrials.gov/show/NCT01570387

Study 10:
NCT Number: NCT01659658
Title: Study of Dexamethasone Plus MLN9708 or Physician's Choice of Treatment in Relapsed or Refractory Systemic Light Chain (AL) Amyloidosis
Recruitment: Not yet recruiting
Study Results: No Results Available
Conditions: Relapsed or Refractory Systemic Light Chain Amyloidosis
Interventions: Drug: MLN9708|Drug: Dexamethasone|Drug: Melphalan|Drug: Cyclophosphamide|Drug: Thalidomide|Drug: Lenalidomide
Sponsor/Collaborators: Millennium Pharmaceuticals, Inc.|Millennium Pharmaceuticals, Inc.
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 3
Enrollment: 248
Funded Bys: Industry
Study Types: Interventional
Study Designs: Allocation: Randomized|Endpoint Classification: Safety/Efficacy Study|Intervention Model: Parallel Assignment|Masking: Open Label|Primary Purpose: Treatment
Other IDs: C16011|2011-005468-10
First Received: August 2, 2012
Start Date: September 2012
Completion Date: August 2018
Last Updated: August 7, 2012
Last Verified: August 2012
Acronym:
Primary Completion Date: May 2018
Outcome Measures: Number of patients with overall hematologic response|2-year vital organ deterioration and mortality rate|Number of patients with complete hematologic response|Overall survival|Progression free survival|Hematologic disease progression free survival|Time to vital organ deterioration and mortality rate|Number of patients with cardiac and/or kidney response|Vital organ progression free survival|Duration of hematologic response|Number of adverse events|Time to treatment failure|Time to subsequent anticancer treatment|Results of Quality of Life Assessment|Number of medical encounters patient experiences|Time to reach plasma concentration|Investigate the association of clinical outcomes and polymorphic genes
URL: http://ClinicalTrials.gov/show/NCT01659658

Study 11:
NCT Number: NCT01078454
Title: Melphalan and Dexamethasone With or Without Bortezomib in Treating Patients With Previously Untreated Systemic Light-Chain Amyloidosis
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Multiple Myeloma and Plasma Cell Neoplasm
Interventions: Drug: bortezomib|Drug: dexamethasone|Drug: melphalan
Sponsor/Collaborators: National Cancer Institute (NCI)|Eastern Cooperative Oncology Group|National Cancer Institute (NCI)
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 3
Enrollment: 98
Funded Bys: Other|NIH
Study Types: Interventional
Study Designs: Allocation: Randomized|Masking: Open Label|Primary Purpose: Treatment
Other IDs: CDR0000664378|ECOG-E4A08
First Received: February 27, 2010
Start Date: November 2010
Completion Date:

Last Updated: August 24, 2012
Last Verified: August 2012
Acronym:
Primary Completion Date: November 2022
Outcome Measures: Hematologic overall response after 3 courses of therapy|Amyloid complete hematologic response rate after 3 courses of therapy and at completion of therapy|Organ response rate after 3 courses of therapy and at 6, 9, and 12 months|Treatment-related mortality|Toxicity|Progression-free and overall survival|Partial response or better at completion of the therapy|Time to hematologic and organ response|Duration of hematologic and organ response|Health-related quality of life
URL: http://ClinicalTrials.gov/show/NCT01078454

Study 12:
NCT Number: NCT00458822
Title: Melphalan and Autologous Stem Cell Transplant Followed By Bortezomib and Dexamethasone in Treating Patients With Previously Untreated Systemic Amyloidosis
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Multiple Myeloma and Plasma Cell Neoplasm
Interventions: Drug: bortezomib|Drug: dexamethasone
Sponsor/Collaborators: National Cancer Institute (NCI)|Memorial Sloan-Kettering Cancer Center|National Cancer Institute (NCI)
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 45
Funded Bys: Other|NIH
Study Types: Interventional
Study Designs: Masking: Open Label|Primary Purpose: Treatment
Other IDs: CDR0000537913|MSKCC-07006
First Received: April 9, 2007
Start Date: February 2007
Completion Date:
Last Updated: March 16, 2011
Last Verified: January 2011
Acronym:
Primary Completion Date: February 2010
Outcome Measures: Response rate at 12 months|Toxicity|Amyloid disease response at 12 and 24 months|Progression-free survival at 12 and 24 months|Overall survival at 12 and 24 months
URL: http://ClinicalTrials.gov/show/NCT00458822

Study 13:
NCT Number: NCT01548573
Title: Tandem Auto Transplantation in Myeloma Patients With <12 Months of Prior Treatment
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Multiple Myeloma
Interventions: Drug: DPACE (Dexamethasone, Cisplatin, Adriamycin, Cyclophosphamide, Etoposide)|Procedure: Transplant 1 (Velcade, Thalidomide, Dexamethasone, Melphalan)|Procedure: Transplant 2 (Velcade, Gemcitabine, Carmustine, Dexamethasone, Melphalan)|Drug: Consolidation VDT-PACE (Velcade, Dexamethasone, Thalidomide, Cisplatin, Adriamycin, Cyclophosphamide, Etoposide)|Drug: Maintenance Year 1 (Velcade, Thalidomide, Dexamethasone OR Velcade, Revlimid, Dexamethasone OR Velcade, Cyclophosphamide, Dexamethasone in 28 day cycles x 12)|Drug: Maintenance Year 2 (Revlimid and Dexamethasone in 28 day cycles x 12)
Sponsor/Collaborators: University of Iowa|University of Iowa|National Cancer Institute (NCI)
Gender: Both
Age Groups: Adult|Senior
Phases: Phase 2
Enrollment: 87
Funded Bys: Other|NIH
Study Types: Interventional
Study Designs: Endpoint Classification: Safety/Efficacy Study|Intervention Model: Single Group Assignment|Masking: Open Label|Primary Purpose: Treatment
Other IDs: 201202818|7R01CA115399
First Received: February 29, 2012
Start Date: May 2012
Completion Date: June 2016
Last Updated: June 6, 2012
Last Verified: June 2012
Acronym:
Primary Completion Date: March 2016
Outcome Measures: Event-Free Survival (EFS)|Identification of Drug Resistant Genes|Number of grade 3 non-hematologic and grade 4 hematologic serious adverse events associated with the addition of bortezomib, thalidomide, and dexamethasone into autologous transplant regimens.|Overall survival
URL: http://ClinicalTrials.gov/show/NCT01548573