HD17 for Intermediate Stage Hodgkin Lymphoma

This study is currently recruiting participants. (see Contacts and Locations)

Verified October 2015 by University of Cologne

Sponsor:
University of Cologne

Information provided by (Responsible Party):
Prof. Dr. Andreas Engert, University of Cologne

ClinicalTrials.gov Identifier:
NCT01356680

First received: May 13, 2011
Last updated: October 30, 2015
Last verified: October 2015
History of Changes

Purpose

This study is designed to test the non-inferiority of the experimental arm compared to the standard arm in terms of progression free survival (PFS).

Condition	Intervention	Phase
Hodgkin Lymphoma	Drug: BEACOPPescalated (Bleomycin, Etoposide, Adriamycin, Cyclophosphamide, Vincristine, Procarbazine, Prednisone) Drug: ABVD (Adriamycin, Bleomycin, Vinblastine, Dacarbazine) Radiation: 30Gy IF-RT (Involved-Field Radiotherapy) Radiation: 30Gy IN-RT (Involved-Node Radiotherapy)	Phase

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: HD17 for Intermediate Stages - Treatment Optimization Trial in the First-Line Treatment of Intermediate Stage Hodgkin Lymphoma

Resource links provided by NLM:

MedlinePlus related topics: Hodgkin Disease Lymphoma

Drug Information available for: Procarbazine Bleomycin sulfate Bleomycin

Genetic and Rare Diseases Information Center resources: Hodgkin Lymphoma Lymphosarcoma

U.S. FDA Resources

Further study details as provided by University of Cologne:

Primary Outcome Measures:

- Progression Free Survival [Time Frame: 3 years] [Designated as safety issue: No]

Secondary Outcome Measures:

- Overall Survival [Time Frame: 3 years] [Designated as safety issue: No]
- CR rate [Time Frame: 6 months] [Designated as safety issue: No]

  Rate of patients achieving a complete remission (CR/CRu) at final restaging after completion of study treatment

Estimated Enrollment: 1100
Study Start Date: December 2011

Estimated Study Completion Date: December 2019
Estimated Primary Completion Date: December 2019 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: Arm A 2 cycles BEACOPPescalated plus 2 cycles ABVD followed by 30Gy IF-RT irrespective of FDG-PET results after chemotherapy	Drug: BEACOPPescalated (Bleomycin, Etoposide, Adriamycin, Cyclophosphamide, Vincristine, Procarbazine, Prednisone) Drug: ABVD (Adriamycin, Bleomycin, Vinblastine, Dacarbazine) Radiation: 30Gy IF-RT (Involved-Field Radiotherapy)
Experimental: Arm B 2 cycles BEACOPPescalated plus 2 cycles ABVD followed by 30Gy IN-RT if FDG-PET is positive after chemotherapy; 2 cycles BEACOPPescalated plus 2 cycles ABVD and treatment stop if FDG-PET is negative after chemotherapy	Drug: BEACOPPescalated (Bleomycin, Etoposide, Adriamycin, Cyclophosphamide, Vincristine, Procarbazine, Prednisone) Drug: ABVD (Adriamycin, Bleomycin, Vinblastine, Dacarbazine) Radiation: 30Gy IN-RT (Involved-Node Radiotherapy)

Eligibility

Ages Eligible for Study: 18 Years to 60 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Hodgkin Lymphoma
- CS I, II with risk factor (stage IIB with risk factor 1 or 2 are not included)
- large mediastinal mass (>1/3 of maximum transverse thorax diameter)
- extranodal involvement
- elevated ESR
- 3 or more involved nodal areas
- written informed consent

Exclusion Criteria:

- Leucocytes <3000/µl
- Platelets < 100000/µl
- Hodgkin Lymphoma as composite lymphoma
- Activity Index (WHO) >2

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01356680

Contacts

Contact: Michael Fuchs ghsg@uk-koeln.de

Locations

Germany

1st Dept. of Medicine, Cologne University Hospital **Recruiting**
Cologne, Germany
Contact: Andreas Engert, Prof. a.engert@uni-koeln.de
Principal Investigator: Andreas Engert, Prof.

Sponsors and Collaborators

University of Cologne

Investigators

Principal Investigator: Andreas Engert, Prof. University of Cologne, German Hodgkin Study Group

More Information

Additional Information:

Homepage GHSG

No publications provided

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Health Authority:	Germany: Federal Institute for Drugs and Medical Devices

Keywords provided by University of Cologne:
Hodgkin Lymphoma
intermediate stage
PET

Additional relevant MeSH terms:

Hodgkin Disease	Liposomal doxorubicin
Lymphoma	Procarbazine
Immune System Diseases	Antibiotics, Antineoplastic
Immunoproliferative Disorders	Antineoplastic Agents
Lymphatic Diseases	Enzyme Inhibitors
Lymphoproliferative Disorders	Molecular Mechanisms of Pharmacological Action
Neoplasms	Pharmacologic Actions
Neoplasms by Histologic Type	Therapeutic Uses
Bleomycin	Topoisomerase II Inhibitors
Doxorubicin	Topoisomerase Inhibitors

ClinicalTrials.gov processed this record on December 01, 2015