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

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: Cyclophosphamide, Prednisone, Vinblastine sulfate, Procarbazine hydrochloride, Procarbazine, Vinblastine, Vincristine sulfate, Dacarbazine, Bleomycin, Doxorubicin, Doxorubicin hydrochloride, Etoposide, Etoposide phosphate
- 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 [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)
<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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<tbody>
<tr>
<td>Active Comparator: Arm A</td>
<td>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)</td>
</tr>
<tr>
<td>Experimental: Arm B</td>
<td>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)</td>
</tr>
</tbody>
</table>

**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 IIIB 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**

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

**Responsible Party:** Prof. Dr. Andreas Engert, German Hodgkin Study Group

**ClinicalTrials.gov Identifier:** NCT01356680 **History of Changes**
<table>
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<tr>
<th>Other Study ID Numbers:</th>
<th>HD17</th>
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<tbody>
<tr>
<td>Study First Received:</td>
<td>May 13, 2011</td>
</tr>
<tr>
<td>Last Updated:</td>
<td>January 25, 2013</td>
</tr>
<tr>
<td>Health Authority:</td>
<td>Germany: Federal Institute for Drugs and Medical Devices</td>
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**Keywords provided by University of Cologne:**
- Hodgkin Lymphoma
- intermediate stage
- PET

**Additional relevant MeSH terms:**
- Hodgkin Disease
- Lymphoma
- Neoplasms by Histologic Type
- Neoplasms
- Lymphoproliferative Disorders
- Lymphatic Diseases
- Immunoproliferative Disorders
- Immune System Diseases
- Bleomycin
- Doxorubicin
- Cyclophosphamide
- Dacarbazine
- Etoposide
- Prednisone
- Procarbazine

- Vinblastine
- Vincristine
- Antibiotics, Antineoplastic
- Antineoplastic Agents
- Therapeutic Uses
- Pharmacologic Actions
- Immunosuppressive Agents
- Immunologic Factors
- Physiological Effects of Drugs
- Antirheumatic Agents
- Antineoplastic Agents, Alkylating
- Alkylating Agents
- Molecular Mechanisms of Pharmacological Action
- Myeloablative Agonists
- Antineoplastic Agents, Phytogenic

ClinicalTrials.gov processed this record on February 14, 2013