Trial record **1 of 1** for: NCT03004833

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Nivolumab and AVD in Early-stage Unfavorable Classical Hodgkin Lymphoma (NIVAHL)

This study is currently recruiting participants.

See Contacts and Locations

Verified April 2017 *by Prof. Dr. Andreas Engert, University of Cologne*

Sponsor:
University of Cologne

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

ClinicalTrials.gov Identifier:
NCT03004833

First received: November 7, 2016
Last updated: April 26, 2017
Last verified: April 2017
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer

How to Read a Study Record

Purpose

The aim of the trial is to improve first-line treatment for early unfavorable cHL by introduction of the anti-PD-1 antibody Nivolumab with a truncated standard chemotherapy (AVD).

The primary objective is to show efficacy of the two experimental treatment strategies. Secondary objectives are to further evaluate efficacy, show safety and feasibility and perform correlative studies.

Condition	Intervention	Phase

Classical Hodgkin Lymphoma	Drug: Nivolumab Drug: Adriamycin Drug: Vinblastine Drug: Dacarbazine	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: None (Open Label)
Primary Purpose: Treatment

Official Title: Nivolumab and AVD in Early-stage Unfavorable Classical Hodgkin Lymphoma

Resource links provided by NLM:

MedlinePlus related topics: Hodgkin Disease Lymphoma

Drug Information available for: Nivolumab

Genetic and Rare Diseases Information Center resources: Lymphosarcoma Hodgkin Lymphoma

U.S. FDA Resources

Further study details as provided by Prof. Dr. Andreas Engert, University of Cologne:

Primary Outcome Measures:

- Complete Remission Rate [Time Frame: 4 to 6 weeks after end of treatment]

Secondary Outcome Measures:

- Treatment related Morbidity [Time Frame: 1 year after end of treatment]
- Progression Free Survival [Time Frame: 1 and 3 years after end of treatment]
- Overall Survival [Time Frame: 1 and 3 years after end of treatment]

Estimated Enrollment: 110
Actual Study Start Date: February 21, 2017
Estimated Study Completion Date: December 2020
Estimated Primary Completion Date: December 2018 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Arm A 4 Cycles of Nivolumab plus AVD followed by IF-RT (30 Gy)	Drug: Nivolumab Infusion of Nivolumab Drug: Adriamycin

	Infusion of Adriamycin Drug: Vinblastine Infusion of Vinblastine Drug: Dacarbazine Infusion of Dacarbazine
Experimental: Arm B 4 Cycles of Nivolumab, followed by 2 cycles of Nivolumab plus AVD, followed by 2 Cycles of AVD followed by IF-RT (30 Gy)	Drug: Nivolumab Infusion of Nivolumab Drug: Adriamycin Infusion of Adriamycin Drug: Vinblastine Infusion of Vinblastine Drug: Dacarbazine Infusion of Dacarbazine

Eligibility

Ages Eligible for Study: 18 Years to 60 Years (Adult)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Histologically proven classical HL
- First diagnosis, no previous treatment
- Age: 18-60 years
- Stage I, IIA with risk factors a-d, IIB with RF c-d:
    1. large mediastinal mass
    2. extranodal lesions
    3. elevated ESR
    4. ≥ 3 nodal areas confirmed by central review.

Exclusion Criteria:

- Composite lymphoma or nodular lymphocyte- predominant Hodgkin lymphoma (NLPHL)
- History of other malignancy ≤ 5 years
- Prior chemotherapy or radiation therapy
- Concurrent disease precluding protocol treatment

- Pregnancy, lactation
- Non-compliance

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: NCT03004833

Contacts

Contact: Michael Fuchs +49-221-480-88200 ghsg@uk-koeln.de

Locations

Germany

University Hospital of Cologne **Recruiting**
Cologne, Germany
Contact: Andreas Engert, Prof.

Sponsors and Collaborators

University of Cologne

Investigators

Principal Investigator: Andreas Engert, Prof. University of Cologne, I. Dept. of Medicine

More Information

Additional Information:

Related Info EXIT

Responsible Party:	Prof. Dr. Andreas Engert, Prof., University of Cologne
ClinicalTrials.gov Identifier:	NCT03004833 History of Changes
Other Study ID Numbers:	Uni-Koeln-2854
Study First Received:	November 7, 2016
Last Updated:	April 26, 2017

Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:

Lymphoma	Antineoplastic Agents
Hodgkin Disease	Immunologic Factors

Neoplasms by Histologic Type
Neoplasms
Lymphoproliferative Disorders
Lymphatic Diseases
Immunoproliferative Disorders
Immune System Diseases
Nivolumab
Liposomal doxorubicin
Doxorubicin
Vinblastine
Antibodies, Monoclonal
Physiological Effects of Drugs
Antibiotics, Antineoplastic
Topoisomerase II Inhibitors
Topoisomerase Inhibitors
Enzyme Inhibitors
Molecular Mechanisms of Pharmacological Action
Antineoplastic Agents, Phytogenic
Tubulin Modulators
Antimitotic Agents
Mitosis Modulators

ClinicalTrials.gov processed this record on September 15, 2017