PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Randomized phase III trial of 1 course BEP (Bleomycin, Etoposid, Cisplatin) versus 2 courses BEP adjuvant chemotherapy in patients with high-risk non-seminomatous germ cell tumors - AH 10/04

Trial Acronym

AH 10/04

URL of the trial

[---]*

Brief Summary in Lay Language

Standard therapy consist of two cycles BEP (Bleomycin, Etoposid und Cisplatin). This study will proof, if the need therapy success can be reached with one cylce BEP only. Reduction of therapy to one cylce could reduce side effects rate, so this rate will be evaluated in the study, too.

Brief Summary in Scientific Language

drug comparison (1 course BEP (Bleomycin, Etoposid, Cisplatin) versus 2 courses BEP) adjuvante chemotherapie in patients with high-risk non-seminomatous germ cell tumor

Organizational Data

- DRKS-ID: **DRKS00003520**
- Date of Registration in DRKS: **2012/04/27**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **53/2004 , Hessen - Ethikkommission bei der Landesärztekammer Hessen**

Secondary IDs

- BfArM-No.: **4022994**

Health condition or Problem studied

- ICD10: **C62 - Malignant neoplasm of testis**
- Free text: **testicular tumor**

Interventions/Observational Groups

- Arm 1: **1 course BEP (Bleomycin, Etoposid, Cisplatin)**

  Cisplatin (Cisplatin Medac): 20 mg/m2 intravenous (30 minutes), days 1-5

  Etoposide (Vepesid®): 100 mg/m2 intravenous (60 minutes), days 1-5

  Bleomycin(Bleomedac®): 30 mg intravenous (bolus), days 2, 8, 15
- Arm 2: **2 course BEP**

  Cisplatin (Cisplatin Medac): 20 mg/m2 intravenous (30 minutes), days 1-5

  Etoposide (Vepesid®): 100 mg/m2 intravenous (60 minutes), days 1-5

  Bleomycin(Bleomedac®): 30 mg intravenous (bolus), days 2, 8, 15

  - the treatment schedule will be repeated on day 22 (3-weekly intervals).

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

Evaluation of the relapse rate in both arms. (Time Frame: 2 years)

Secondary Outcome

- To evaluate treatment related acute and long-term toxicity. (parameter: Toxicities according to NCI / CTC Grade 3 Grade 4, Hematology, Audiometry, Pulmonary Function, Creatinine Clearance) --> Measurement time points: Follow-up Visit 1 (6 weeks after chemotherapy), Follow-up Visit (every 3 month)
- To evaluate overall and disease-free survival. (Time Frame: 5 years)
- To document health economical data concerning cost of treatment (number, methods and duration of follow up investigations dependent on the number, time, and location of relapses).

Countries of recruitment

- DE **Germany**
- PL **Poland**
- BE **Belgium**
- AU **Australia**
- NL **Netherlands**
- NO **Norway**
- SK **Slovakia**
- ES **Spain**
- UK **[---]***
- FR **France**
- TR **Turkey**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2004/10/10**
- Target Sample Size: **580**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Male**
- Minimum Age: **16 Years**
- Maximum Age: **59 Years**

Additional Inclusion Criteria

- Histologically proven non-seminomatous germ cell tumor of the testis
- Hostologically proven vascular invasion of the primary tumor into testicular veins or lymphatics
- Clinical stage I patients (exclusion of persisting marker elevation after ablation of the testicle. lymph node metastases by CT of the abdomen and chest)
- WHO performance status 0, 1, or 2
- Creatinune clearance > 40 ml/min
- WBC > 3.0 G/l and platelets > 100 G/l
- No previous chemotherapy
- Contralateral TIN is allowed if the contralateral testis will be treated by radiation after repeat positive biopsy after chemotherapy
- Before patient registration and randomisation, informed consent must be given according to ICH/EU GCP, and national/local regulations

Exclusion criteria

- All patients with seminoma
- All patients with non-seminoma > clinical stage I
- All patients with missing vascular invasion
- Previous chemotherapy
- Patients with secondary malignancy except contralateral TIN and contralateral germ cell tumor treated by ablation and subsequent surveillance of more than 3 years
- Intersex
- WHO PS 3 and 4
- Patients with renal function impairment (creatinine clearance <= 40 ml/min
- Patients with liver function impairment (bilirubin > 1.25 x N and / or ASAT > 2 x N)
- Patients with impaired pulmonary funktion according to pulmonary function test
- Patients with serious illness or medical conditions incompatible with the protocol

Addresses

■ **Primary Sponsor**

Deutsche Krebshilfe e.V.
Buschstr. 32
53113 Bonn
Germany

Telephone: **02 28/7 29 90–0**
Fax: **02 28/7 29 90–11**
E-mail: **deutsche at krebshilfe.de**
URL: **www.krebshilfe.de**

■ **Contact for Scientific Queries**

Universitätsklinikum Düsseldorf
Mr. Prof. Dr. med. Peter Albers
Moorenstraße 5

Contact for Scientific Queries

Universitätsklinikum Düsseldorf
Mr. Prof. Dr. med. Peter Albers
Moorenstraße 5
40225 Bilk, Düsseldorf
Germany

Telephone: **0211/811-81 10**
Fax: **0211/811-86 76**
E-mail: **sekrurol at uni-duesseldorf.de**
URL: **[---]***

- **Contact for Public Queries**

Universitätsklinikum Düsseldorf
Mr. Prof. Dr. med. Peter Albers
Moorenstraße 5
40225 Bilk, Düsseldorf
Germany

Telephone: **0211/811-81 10**
Fax: **0211/811-86 76**
E-mail: **sekrurol at uni-duesseldorf.de**
URL: **[---]***

Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

Klinikum Kassel
Mönchebergstraße 41-43
34125 Kassel
Germany

Telephone: **0561 980-0**
Fax: **0561 980-6988**
E-mail: **[---]***
URL: **http://www.klinikum-kassel.de/**

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.