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

## Trial Description

### Title

**Prospectively randomized, double-blind, multicenter phase II trial comparing the efficacy of chemotherapy with gemcitabine plus cisplatin and sorafenib versus gemcitabine plus cisplatin and placebo in the treatment of advanced or metastatic urothelial carcinoma SUSE - AB 31/05**

### Trial Acronym

**SUSE - AB 31/05**

### URL of the trial

**[---]***

### Brief Summary in Lay Language

**Trial comparing the efficacy of chemotherapy with gemcitabine plus cisplatin and sorafenib versus gemcitabine plus cisplatin and placebo in the treatment of advanced or metastatic urothelial carcinoma.**
**This study is based on the hypothesis that sorafenib can improve the efficacy of combination chemotherapy in patients with advanced urothelial cancer.**
**The main target is the 5 year survival free of recurrent disease.**
**Potential study participants are patients with advanced bladder cancer.**

### Brief Summary in Scientific Language

**Trial comparing the efficacy of chemotherapy with gemcitabine plus cisplatin and sorafenib versus gemcitabine plus cisplatin and placebo in the treatment of advanced or metastatic urothelial carcinoma.**

### Do you plan to share individual participant data with other researchers?

**[---]***

### Description IPD sharing plan

**[---]***

## Organizational Data

- DRKS-ID: **DRKS00003397**

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- Date of Registration in DRKS: **2012/01/13**
- Date of Registration in Partner Registry or other Primary Registry: **2010/10/01**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **06-2998 , Ethik-Kommission der Medizinischen Fakultät der Universität Duisburg-Essen**

## Secondary IDs

- EudraCT-Number: **2005-006098-29**
- Primary Registry-ID: **NCT01215266 (clinical-trials.gov)**
- BfArM-No.: **4031573**

## Health condition or Problem studied

- ICD10: **C67 - Malignant neoplasm of bladder**
- Free text: **bladder cancer**

## Interventions/Observational Groups

- Arm 1: **- Gemcitabin 1250 mg/m2, day 1 + 8, intravenous**
  **- Cisplatin 70 mg/m2, day 2, intravenous**
  **- Sorafenib 2 x 400 mg, day 3 - 21, orally**
- Arm 2: **- Gemcitabin 1250 mg/m2, day 1 + 8, intravenous**
  **- Cisplatin 70 mg/m2, day 2, intravenous**
  **- Placebo 2 x 2 tablets, day 3 - 21, orally**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Double or multiple blind**
- Who is blinded: **[---]***
- Control: **Placebo**
- Purpose: **Treatment**
-

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **Double or multiple blind**

Who is blinded: **[---]***

Control: **Placebo**

Purpose: **Treatment**

Assignment: **Parallel**

- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **Yes**

### Primary Outcome

**Progression free survival [ Time Frame: 5 years ]**

### Secondary Outcome

**- Response rates, time of response [ Time Frame: 5 years ]**
**- Time to progression [ Time Frame: 5 years ]**
**- Overall survival [ Time Frame: 5 years ]**
**- Evaluation and comparison in both treatment arms [ Time Frame: 5 years ]**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- University Medical Center **Charité - Universitätsmedizin Berlin - Campus Benjamin Franklin, Berlin**
- University Medical Center **Johanniter-Krankenhaus, Stendal**
- University Medical Center **Universitätsklinikum Kassel, Kassel**
- University Medical Center **Universitätsklinikum Weiden, Weiden**
- University Medical Center **Krankenhaus St. Georg, Hamburg**
- University Medical Center **Technische Universität, München**
- University Medical Center **Urologie, Köln**

- University Medical Center **Uniklinikum Dresden C.G.C. Urologie, Dresden**
- University Medical Center **Urologie, Münster**
- University Medical Center **Urologie, Düsseldorf**
- Medical Center **Klinik für Allgemeine Chirurgie, Viszeral-, Gefäß- und Kinderchirurgie, Saarland**
- University Medical Center **Universitätsklinikum Essen, Essen**
- University Medical Center **Eppendorf Urologie, Hamburg**
- University Medical Center **Urologische Klinik und Poliklinik, Saarland**
- University Medical Center **Urologie, Tübingen**
- University Medical Center **Urologische Klinik, Ulm**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2006/10/09**
- Target Sample Size: **132**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **99 Years**

### Additional Inclusion Criteria

**- Condition ECOG(Eastern Cooperative Oncology Group) 0-1**
**- Life expectancy at least 12 weeks**
**- Women in conceptional age: negative pregnancy test and adequate contraception (oral contraceptive, spiral); at men adequate contraception of the man (condom use) to 3 months after discontinuation of therapy with sorafenib**
**- Histologically or cytologically proven urothelial carcinoma of the bladder or upper urinary tract**
**- Locally advanced or metastatic urothelial carcinoma of the bladder or upper urinary tract (T3b,T4/ N+/M+)**
**- At least one unidimensional measurable lesion on CT(Computed Tomography) or MRI(Magnetic resonance imaging) according to RECIST(Response Evaluation Criteria in Solid Tumors) criteria**
**- Adequate hematologic, renal, hepatic and coagulation-physiological functions**

### Exclusion criteria

**- Absence of the above inclusion criteria**
**- Dialysis after nephrectomy**
**- Patients with brain tumors and / or brain metastases**
**- Previous or existing serious cardiovascular (grade III - IV according to NYHA(New York Heart Association)) disease, active angina pectoris or ischemia, myocardial infarction within 6 months prior to enrollment, or patients with serious cardiac arrhythmias requiring antiarrhythmic therapy (beta blockers and digoxin are permitted)**
**- Patients with uncontrolled high blood pressure, systolic blood pressure> 150 mm Hg or diastolic pressure> 90 mmHg despite optimal medical treatment**
**- Patients with thrombotic or embolic events such as stroke or pulmonary embolism**
**- Patients with recently or known bleeding diathesis**
**- Known significant neurological or psychiatric diseases including dementia and epileptic seizures**
**- Serious inflammatory eye disease, hearing impairment**
**- Pulmonary (pO2(Blood oxygen) <60 mm Hg(Millimeters of mercury)), hematopoietic (eg(exempli gratia) severe bone marrow aplasia), hepatic or renal disease**
**- Patients with poorly controlled diabetes mellitus**
**- Serious bacterial or fungal infections(>Grade 2 NCI-CTC(National Cancer Institute-Common Terminology Criteria) Version 3)**
**- chronic hepatitis B or C, HIV(human immunodeficiency virus) infection**
**- Autoimmune disease**

## Addresses

■ **Primary Sponsor**

**Universitätsklinikum Essen**
**Hufelandstraße 55**
**45147 Essen**
**Germany**

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Fax: **[---]***
E-mail: **[---]***
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■ **Contact for Scientific Queries**

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## Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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**Mr.**
**Gebäude K56**
**51368 Leverkusen**
**Germany**

Telephone: **0214 / 30-1**
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

## Status

■ Recruitment Status: **Recruiting stopped after recruiting started**

- 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.*