Resection of Pulmonary Metastasis in Clear Cell Renal Cell Carcinoma +/- Adjuvant Sunitinib Therapy (SMAT)

This study is currently recruiting participants.

Verified February 2012 by Association of Urogenital Oncology (AUO)

First Received on October 6, 2010. Last Updated on February 10, 2012  History of Changes

Purpose

The aim is to identify biomarkers in the blood, to indicate early response or early treatment resistance.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal Cell Carcinoma</td>
<td>Drug: Sunitinib</td>
<td>Phase II</td>
</tr>
<tr>
<td>Pulmonary Metastases</td>
<td>Drug: Placebo</td>
<td></td>
</tr>
</tbody>
</table>

Study Type: Interventional  
Study Design: Allocation: Randomized  
Endpoint Classification: Safety/Efficacy Study  
Intervention Model: Parallel Assignment  
Masking: Double Blind (Subject, Investigator)  
Primary Purpose: Treatment

Official Title: Prospektiv Randomisierte Multizentrische Phase II-Studie Zur Metastasenresektion Von Lun genfiliae (Poor-prognosis) Beim Klarzelligen Nierenzellkarzinom +/- Adjuvante Sunitinibtherapie über 1 Jahr SMAT - AN 20/04 Der AUO

Resource links provided by NLM:
- Drug Information available for: Sunitinib malate  
  Sunitinib

U.S. FDA Resources

Further study details as provided by Association of Urogenital Oncology (AUO):

Primary Outcome Measures:
- 2 year relapse-free survival [ Time Frame: 5 years ] [ Designated as safety issue: Yes ]

Secondary Outcome Measures:
- perioperative mortality and morbidity [ Time Frame: 5 years ] [ Designated as safety issue: No ]
- Side effect of adjuvant therapy [ Time Frame: 5 years ] [ Designated as safety issue: No ]
- Quality of Life of the Patient [ Time Frame: 5 years ] [ Designated as safety issue: Yes ]
- Overall Survival [ Time Frame: 5 years ] [ Designated as safety issue: No ]

Estimated Enrollment: 60  
Study Start Date: October 2010  
Estimated Study Completion Date: October 2015  
Estimated Primary Completion Date: October 2015 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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</table>
| Active Comparator: Sunitinib one year adjuvant treatment with sunitinib | Drug: Sunitinib one-year adjuvant Treatment with Sunitinib, schematic (4:2): 4 weeks (28) 50 mg(milligram) daily, 2 weeks (14) break  
  Other Name: adjuvant Treatment |
| Placebo Comparator: Placebo | Drug: Placebo                                                                                                                                           |
**Eligibility**

**Inclusion Criteria:**
- $\geq 2$ synchronous or within 24 Months after Nephrectomy occurred pulmonary metastases. Patients in whom more back than 2 years of a solitary lung metastasis, bone metastasis or brain metastasis was resected, may also be included in the study.
- Aged 18 to 75 years
- functionally acceptable surgical risk
- Women in conceptional age: negative pregnancy test and adequate contraception
- Adequate hematologic, renal, hepatic and coagulation-physiological functions
- Amylase/ Lipase $< 1.5 \times$ upper limit of normal
- Informing the patient about the study and the present written consent to participate after clarification in accordance with the stipulations of AMG (German drug law), and the principles of GCP ("informed consent")
- Patient compliance and geographic proximity to allow adequate follow-up

**Exclusion Criteria:**
- Presence of other metastases outside the lung
- progress in the 12-week sunitinib therapy before resection of metastases
- R1 or R2-finding in resection of metastases
- Dialysis after nephrectomy
- Previous or existing serious cardiovascular (grade III - IV according to NYHA (New York Heart Association)) disease, active angina pectoris or ischemia, myocardial infarction within previous 6 months, uncontrolled hypertension (RR diastolic $\geq 120 \text{ mmHg}$ (Millimeters of mercury))
- serious hematopoetic (e.g. serious Bone marrow aplasia), pulmonary, hepatic or renal Disease
- Stroke within the previous six months
- Patients with poorly controlled diabetes mellitus
- Serious bacterial or fungal infections
- chronic hepatitis B or C, HIV (human immunodeficiency virus) infection
- autoimmune disease
- prior organ transplantation
- prior autologous bone marrow transplant or stem cell transferred within the last 4 months before study
- Neuropsychiatric diseases that affect patient compliance
- Manifesto, second malignancy or other malignancy within the past 5 years (except basal cell carcinoma, carcinoma in situ of the cervix, incidental prostate carcinoma, superficial urothelial Ca pTaG1-2 and pT1G1)
- Therapy with immunotherapeutic agents including monoclonal antibodies, cytotoxic drugs or hormones (other than bisphosphonates and oral contraceptives) within the last 4 weeks prior to enrollment. Previous use of inhibitors of Ras/Raf-, MEK kinase, AKT kinase and mTOR inhibitors or induction of Farnesyltransferase
- Previous use of angiogenesis inhibitors such as VEGF / VEGFR, PDGF / PDGFR and other key molecules of angiogenesis
- parallel treatment with rifampicin
- Participation in other treatment studies in the last 4 weeks

**Contacts and Locations**

Please refer to this study by its ClinicalTrials.gov identifier: NCT01216371

**Contacts**
- Contact: Susanne Krege, Priv. Doz. Dr. med. 02 151 / 334-23 81

**Locations**

**Germany**
- Helios Klinikum Emil von Behring
- Berlin, Germany, 14165
- Contact: Kollmeier Jens, Dr. med. 030/81 02-14 47
- Sub-Investigator: Jens Kollmeier, Dr. med.
- Sub-Investigator: Bettina Schlaut, Dr. med.
Resection of Pulmonary Metastasis in Clear Cell Renal Cell Carcinoma +/- Adjuvant S...

http://clinicaltrials.gov/ct2/show/NCT01216371
Sub-Investigator: Klaudia Fischbach

**Sponsors and Collaborators**
Association of Urogenital Oncology (AUO)
University Hospital, Essen

**Investigators**
Principal Investigator: Susanne Krege, Priv. Doz. Dr. med. urological hospital of Maria Hill Krankenhaus Krefeld

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### More Information

No publications provided

| Responsible Party | Heidrun Rexer, Priv. Doz. Dr. med. Susanne Krege, urological hospital of Maria Hill Krankenhaus Krefeld, Association of Urogenital Oncology (AUO) |
| ClinicalTrials.gov Identifier | NCT01216371 |
| Other Study ID Numbers | AN 20/04, 2008-007609-38 |
| Study First Received | October 6, 2010 |
| Last Updated | February 10, 2012 |
| Health Authority | Germany: Federal Institute for Drugs and Medical Devices |

Keywords provided by Association of Urogenital Oncology (AUO):
- carcinoma
- metastases
- renal
- lung

Additional relevant MeSH terms:
- Carcinoma
- Carcinoma, Renal Cell
- Neoplasm Metastasis
- Lung Neoplasms
- Neoplasms, Glandular and Epithelial
- Neoplasms by Histologic Type
- Neoplasms
- Adenocarcinoma
- Kidney Neoplasms
- Urologic Neoplasms
- Urogenital Neoplasms
- Neoplasms by Site
- Kidney Diseases
- Urologic Diseases
- Neoplastic Processes
- Pathologic Processes
- Respiratory Tract Neoplasms
- Thoracic Neoplasms
- Lung Diseases
- Respiratory Tract Diseases
- Adjuvants, Immunologic
- Sunitinib
- Immunologic Factors
- Physiological Effects of Drugs
- Pharmacologic Actions
- Antineoplastic Agents
- Therapeutic Uses
- Angiogenesis Inhibitors
- Angiogenesis Modulating Agents
- Growth Substances

ClinicalTrials.gov processed this record on February 14, 2012