Study 1 of 1 for search of: Everolimus (RAD001) in Combination With Intravenous Carboplatin in Taxane- and Anthracycline-Pretreated Patients With Progressive Metastatic Breast Cancer

Everolimus (RAD001) and Carboplatin in Pretreated Metastatic Breast Cancer

The recruitment status of this study is unknown because the information has not been verified recently.

Verified June 2010 by Charite University, Berlin, Germany. Recruitment status was Recruiting

First Received on June 18, 2009. Last Updated on January 25, 2011  History of Changes

| Sponsor: Charite University, Berlin, Germany |
| Collaborators: KKS-Charité, Koordinierungszentrum für Klinische Studien Novartis Pharmaceuticals |
| Information provided by: Charite University, Berlin, Germany |
| ClinicalTrials.gov Identifier: NCT00930475 |

Purpose

This is an open-label, mono-center phase I/II study designed to determine the maximum tolerated dose (MTD) and dose-limiting toxicities (DLT) of RAD001 in combination with carboplatin in taxane- and anthracycline-pretreated patients with progressive metastatic breast cancer. Additionally, the study is designed to characterize the safety, the tolerability and efficacy of this study.

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<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
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<tr>
<td>Breast Cancer</td>
<td>Drug: RAD001 (Everolimus) in combination with carboplatin</td>
<td>Phase 1 Phase 2</td>
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Study Type: Interventional
Study Design: Allocation: Non-Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Everolimus (RAD001) in Combination With Intravenous Carboplatin in Taxane- and Anthracycline-pretreated Patients With Progressive Metastatic Breast Cancer

Resource links provided by NLM:
- Genetics Home Reference related topics: breast cancer
- MedlinePlus related topics: Breast Cancer Cancer
- Drug Information available for: Carboplatin Sirolimus Everolimus Temsirolimus
- U.S. FDA Resources

Further study details as provided by Charite University, Berlin, Germany:

Primary Outcome Measures:
- Phase I: dose limiting toxicity [ Time Frame: after three weeks ] [ Designated as safety issue: Yes ]
• Phase II: response rate [ Time Frame: every six weeks ] [ Designated as safety issue: No ]

Secondary Outcome Measures:
• Phase I: adverse events [ Time Frame: after three weeks ] [ Designated as safety issue: Yes ]

Estimated Enrollment: 54
Study Start Date: February 2009
Estimated Primary Completion Date: December 2010 (Final data collection date for primary outcome measure)

Intervention Details:

Drug: **RAD001 (Everolimus)** in combination with **carboplatin**
phase I: dose levels: 2.5 mg, 5 mg, 7.5 mg and 10 mg daily in combination with **carboplatin**
AUC2 weekly until progress

Drug: **RAD001 (Everolimus)** in combination with **carboplatin**
phase 2: 10 mg **RAD001** in combination with **carboplatin**

**Detailed Description:**
During the phase I part the study will include at least 3 patients at each dose-level until MTD is reached. Each cohort will consist of newly enrolled patients. Intra-patient dose escalation is not permitted. Once MTD is reached a total of 6 patients will be treated at MTD (phase I). For the phase II the minimax two-stage design will be applied. After testing the drug on 16 patients in the first stage of phase II, the trial will be terminated if 1 or fewer respond (SD, PR, CR). If the trial goes on to the second stage, a total of 34 patients will be studied during the phase II part.

**Eligibility**

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Female
Accepts Healthy Volunteers: No

**Criteria**
**Inclusion Criteria:**
• adult female patients
• at least two prior chemotherapies due to metastatic or inoperable breast cancer
• Karnofsky performance status of at least 60%
• pretreatment with at least one taxane and one anthracycline

**Exclusion Criteria:**
• previous treatment with mTOR-inhibitors, carboplatin, cisplatin or oxaliplatin
• inadequate organ function including bone marrow function
• bleeding tumours
• known uncontrolled metastases in CNS or carcinomatous meningosis
• patients who have been treated during the last five days with inhibitors or inducers of CYP3A
• serious pulmonary, neurological, endocrinological or other disorders interfering with this study medication, especially patients with known lung fibrosis, emphysema or severe COPD

**Contacts and Locations**

Please refer to this study by its ClinicalTrials.gov identifier: NCT00930475

Contacts

Contact: Jan Eucker, Dr. med. jan.eucker@charite.de

Locations

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Sponsors and Collaborators
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