ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Trial record **2 of 8** for: temsirolimus | Completed | Studies With Results | renal cell carcinoma | United States | Adult, Senior

Previous Study | Return to List | Next Study

Temsirolimus Versus Sorafenib As Second-Line Therapy In Patients With Advanced RCC Who Have Failed First-Line Sunitinib (INTORSECT)

This study has been completed.

Sponsor:
Pfizer

Information provided by (Responsible Party):
Pfizer

ClinicalTrials.gov Identifier:
NCT00474786

First received: May 15, 2007
Last updated: October 28, 2013
Last verified: October 2013
History of Changes

Full Text View | **Tabular View** | **Study Results** | Disclaimer | How to Read a Study Record

Purpose

This is an international, randomized, open-label, outpatient, multicenter study. Subjects will be assigned in a 1:1 ratio to 1 of 2 treatment arms: **temsirolimus** 25 mg once weekly by intravenous (IV) infusion or sorafenib 400 mg by mouth (PO) twice daily (BID). These investigational drugs will be administered in 6-week cycles for the duration of the study, up to 24 months. Subjects will be stratified by nephrectomy status, duration of response to sunitinib therapy, Memorial Sloan Kettering Cancer Center (MSKCC) prognostic group, and RCC tumor histology.

Condition	Intervention	Phase
Renal Cell Carcinoma	Drug: Sorafenib Drug: **temsirolimus** (**Torisel**)	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Randomized Trial Of **Temsirolimus** Versus Sorafenib As Second-Line Therapy In Patients With Advanced **Renal Cell Carcinoma** Who Have Failed First-Line Sunitinib Therapy

Resource links provided by NLM:

MedlinePlus related topics: Cancer

Drug Information available for: Sirolimus Everolimus Temsirolimus Sorafenib Sunitinib malate Sorafenib tosylate Sunitinib

Genetic and Rare Diseases Information Center resources: Kidney Cancer Renal Cancer

U.S. FDA Resources

Further study details as provided by Pfizer:

Primary Outcome Measures:

- Progression-Free Survival (PFS) [Time Frame: Baseline up to 24 Months] [Designated as safety issue: Yes]

  Interval from date of randomization until documentation of progressive disease (PD) by an independent tumor assessment according to Response Evaluation Criteria in Solid Tumor (RECIST) or death for any reason whichever occurred first.

Secondary Outcome Measures:

- Progression Free Survival (PFS) by Investigator Assessment [Time Frame: Baseline up to 24 Months] [Designated as safety issue: No]

  Interval from date of randomization until documentation of PD by an investigator tumor assessment, symptomatic deterioration, or death for any reason whichever occurred first.

- Percentage of Participants With Tumor Response [Time Frame: Baseline up to 24 Months] [Designated as safety issue: No]

  Percentage of participants with tumor response based on assessment of confirmed complete response (CR) or confirmed partial response (PR) according to RECIST and evaluated by independent central review. CR/PR persisted on repeat imaging study at least 4 weeks after initial documentation of response. PR had at least 30 percent decrease in the sum of the longest diameter (LD) of target lesions taking as reference the baseline sum LD.

- Overall Survival (OS) [Time Frame: Baseline to date of death from any cause (up to 24 months)] [Designated as safety issue: No]

  Overall survival was the duration from randomization to death. For participants who are alive, overall survival was censored at the last contact.

- Percentage of Participants With PFS Events at 12, 24 and 36 Weeks by Independent Assessment [Time Frame: Weeks 12, 24, and 36] [Designated as safety issue: No]

  PFS: Interval from date of randomization until documentation of PD by an independent tumor assessment according to RECIST or death for any reason whichever occurred first. PFS calculated as (Weeks)=(randomization date minus first dose date plus 1) divided by 7.

- Duration of Response (DR) [Time Frame: Baseline up to 24 Months] [Designated as safety issue: No]

  Duration of response as defined by the time from CR or PR (whichever status recorded first) until the date of death or PD was objectively documented. Median and its 95 percent confidence interval (95% CI) were estimated using Kaplan-Meier method.

Other Outcome Measures:

- Number of Participants With Adverse Events (AEs) and Serious Adverse Events (SAEs) [Time Frame: Baseline up to 24 months] [Designated as safety issue: Yes]

  Counts of participants who had treatment-emergent adverse events (TEAEs), defined as newly occurring or worsening after first dose. Relatedness to [study drug] was assessed by the investigator (Yes/No). Participants with multiple occurrences of an AE within a category were counted once within the category.

Enrollment:	512
Study Start Date:	September 2007
Study Completion Date:	January 2013
Primary Completion Date:	January 2012 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1	Drug: Sorafenib Subjects randomized to arm B will take sorafenib 400 mg (2 x 200 mg tablets) PO, BID (total daily dose of 800 mg).
Experimental: 2	Drug: **temsirolimus** (**Torisel**) Subjects randomized to arm A will receive **temsirolimus** (**Torisel**) 25 mg via IV infusion once weekly. This infusion is to be administered over a 30-60 minute period. Subjects are to be pre-treated with 25-50 mg IV diphenhydramine (or comparable IV antihistamine) approximately 30 minutes before **temsirolimus** infusion. Other Name: **temsirolimus** (**Torisel**)

Eligibility

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

Criteria

Inclusion Criteria:

- Histologically confirmed diagnosis of mRCC (regardless of histology or nephrectomy status) with well-documented Radiological PD by RECIST criteria or clinical PD as judged by the investigator while receiving first-line sunitinib therapy. Subjects must have at least 1 cycle of sunitinib therapy (minimum of four weeks continuously).

- At time of randomization, at least 2 weeks since prior treatment with sunitinib, palliative radiation therapy, and/or surgery.
- At time of randomization, there must be at least 1 measurable lesion per RECIST. Lesions that have been previously irradiated or embolized cannot be selected as target lesions.
  - More criteria apply

Exclusion Criteria:

- Metastatic CNS from RCC.
- Subjects who discontinued Sutent therapy due specifically to intolerance.
- Prior systemic therapy for mRCC other than sunitinib.
- Active ketonuria, secondary to poorly controlled diabetes mellitus
  - More criteria apply

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00474786

Show 128 Study Locations

Sponsors and Collaborators

Pfizer

Investigators

Study Director: Pfizer CT.gov Call Center Pfizer

More Information

Additional Information:

To obtain contact information for a study center near you, click here.

No publications provided

Responsible Party:	Pfizer
ClinicalTrials.gov Identifier:	NCT00474786 History of Changes
Other Study ID Numbers:	3066K1-404, B1771003
Study First Received:	May 15, 2007
Results First Received:	January 31, 2013
Last Updated:	October 28, 2013
Health Authority:	United States: Food and Drug Administration

Keywords provided by Pfizer:
Metastatic or Advanced **Renal Cell Carcinoma**

Additional relevant MeSH terms:

Carcinoma	Sunitinib
Carcinoma, **Renal Cell**	Antibiotics, Antineoplastic
Kidney Neoplasms	Antineoplastic Agents
Kidney Diseases	Therapeutic Uses
Sirolimus	Pharmacologic Actions
Everolimus	Antifungal Agents
Neoplasms, Glandular and Epithelial	Anti-Infective Agents
Neoplasms by Histologic Type	Immunosuppressive Agents
Neoplasms	Immunologic Factors
Adenocarcinoma	Physiological Effects of Drugs
Urologic Neoplasms	Anti-Bacterial Agents
Urogenital Neoplasms	Protein Kinase Inhibitors
Neoplasms by Site	Enzyme Inhibitors
Urologic Diseases	Molecular Mechanisms of Pharmacological Action
Sorafenib	Angiogenesis Inhibitors

ClinicalTrials.gov processed this record on March 27, 2014