Trial record **1 of 1** for: NCT00009919
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SU5416 in Treating Patients With Metastatic Kidney Cancer That Has Not Responded to Previous Treatment

This study has been terminated.
(Administratively complete.)

Sponsor:
National Cancer Institute (NCI)

Information provided by (Responsible Party):
National Cancer Institute (NCI)

ClinicalTrials.gov Identifier:
NCT00009919

First received: February 2, 2001
Last updated: January 22, 2013
Last verified: January 2013
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

Phase II trial to study the effectiveness of SU5416 in treating patients who have metastatic kidney cancer that has not responded to previous therapy with interleukin-2. SU5416 may stop the growth of kidney cancer by stopping blood flow to the tumor

Condition	Intervention	Phase
Recurrent Renal Cell Cancer Stage IV Renal Cell Cancer	Drug: semaxanib	Phase 2

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

Official Title: Phase II Study of SU5416 (NSC 696819) for Patients With Progressive Metastatic Renal Cancer Failing Prior Biologic Therapy or 5-Fluorouracil Containing Regimens

Resource links provided by NLM:

MedlinePlus related topics: Cancer Kidney Cancer

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

U.S. FDA Resources

Further study details as provided by National Cancer Institute (NCI):

Primary Outcome Measures:

- Rate of progression-free events [Time Frame: 6 months] [Designated as safety issue: No]
  Estimated with associated confidence intervals using standard methods such as chi-square and Fisher's exact tests.
- Objective response rate [Time Frame: Up to 3 years] [Designated as safety issue: No]
  Estimated with associated confidence intervals using standard methods such as chi-square and Fisher's exact tests.

Secondary Outcome Measures:

- Survival [Time Frame: Up to 3 years] [Designated as safety issue: No]

  Analyzed using Kaplan Meier curves and Cox proportional hazards models.

- Time to disease progression [Time Frame: Up to 3 years] [Designated as safety issue: No]

  Analyzed using Kaplan Meier curves and Cox proportional hazards.

- Time to treatment failure [Time Frame: Up to 3 years] [Designated as safety issue: No]

  Analyzed using Kaplan Meier curves and Cox proportional hazards.

- Duration of response [Time Frame: Up to 3 years] [Designated as safety issue: No]

  Analyzed using Kaplan Meier curves and Cox proportional hazards.

Enrollment: 50
Study Start Date: December 2000
Primary Completion Date: June 2003 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Treatment (semaxanib) Patients receive SU5416 IV over 1 hour twice weekly. Treatment continues every 6 weeks for at least 2 courses in the absence of disease progression or unacceptable toxicity. Patients with CR receive an additional 6 months of therapy after achieving CR.	Drug: semaxanib Given IV Other Names: • semoxind • SU5416 • Sugen 5416

Detailed Description:

OBJECTIVES:

I. Determine the clinical activity of SU5416 in patients with progressive metastatic renal cancer failing prior biologic therapy or fluorouracil-containing regimens.

II. Determine the changes in tumor perfusion in patients treated with this regimen.

III. Determine the time to progression and survival in patients treated with this regimen.

OUTLINE:

Patients receive SU5416 IV over 1 hour twice weekly. Treatment continues every 6 weeks for at least 2 courses in the absence of disease progression or unacceptable toxicity. Patients with complete response (CR) receive an additional 6 months of therapy after achieving CR.

Patients are followed every 3 months.

Eligibility

Ages Eligible for Study: 16 Years and older (Child, Adult, Senior)
Genders Eligible for Study: Bo h
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Histologically confirmed metastatic renal cell carcinoma
- Prior removal of primary tumors
- Bidimensionally measurable disease
  - Bone-only disease is not considered measurable
- Progressive disease following no more than 2 prior biologic therapy (e.g.,interleukin-2, interferon alfa, vaccine, or dendritic cell therapy) orfluorouracil-containing (single-agent or in combination therapy) regimens
- No known history of CNS metastasis unless all of the following are true:
  - Previously treated

- Neurologically stable
- No requirement for IV steroids or anticonvulsants
- No requirement for oral steroids and no evidence of active or residual CNS disease on CT scan or MRI

- Negative brain scan (CT scan or MRI) required if neurologic signs or symptoms suggestive of CNS metastasis present
- Performance status - Zubrod 0-2
- At least 12 weeks
- Absolute neutrophil count at least 1,500/mm^3
- Platelet count greater than 100,000/mm^3
- Bilirubin no greater than 1.5 mg/dL
- SGPT no greater than 2.5 times upper limit of normal
- PT and PTT normal
- Fibrinogen normal
- D-Dimer assay normal
- Creatinine no greater than 1.5 mg/dL
- Creatinine clearance at least 60 mL/min
- See Surgery
- No active congestive heart failure
- No uncontrolled angina
- No myocardial infarction or severe/unstable angina within the past 6 months
- No uncontrolled hypertension
- No uncompensated coronary artery disease on electrocardiogram or physical examination
- No severe peripheral vascular disease
- No deep vein or arterial thrombosis within the past 3 months
- No pulmonary embolism wi hin the past 3 months
- Not pregnant or nursing
- Negative pregnancy test
- Fertile patients must use effective contraception
- No concurrent serious infection
- No overt psychosis, mental disability, or incompetence
- No diabetes mellitus
- No other prior malignancy within he past 5 years except curatively treated nonmelanoma skin cancer or carcinoma in situ of the cervix
- No hypersensitivity or allergic reaction to paclitaxel
- See Disease Characteristics
- No other concurrent anti-cancer biologic therapy
- See Disease Characteristics
- No concurrent anti-cancer chemotherapy
- See Disease Characteristics
- At least 4 weeks since prior radiotherapy and recovered
- No sole indicator lesion within the previously irradiated port
- No concurrent anti-cancer radiotherapy
- See Disease Characteristics
- At least 4 weeks since prior major surgery and recovered
- At least 1 year since prior bypass surgery for atherosclerotic coronary artery disease
- No concurrent surgery for cancer
- No other inves igational drugs (e.g., analgesics or antiemetics) for at least 28 days prior to and after study

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to his study by its ClinicalTrials.gov iden ifier: NCT00009919

Locations

United States, Texas

M D Anderson Cancer Center
Houston, Texas, United States, 77030

Sponsors and Collaborators

National Cancer Ins itute (NCI)

Investigators

Principal Investigator: Arlene Siefker-Radtke M.D. Anderson Cancer Center

More Information

Responsible Party:	National Cancer Institute (NCI)
ClinicalTrials.gov Identifier:	NCT00009919 History of Changes
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Study First Received:	February 2, 2001
Last Updated:	January 22, 2013
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Carcinoma, Renal Cell	Urologic Diseases
Adenocarcinoma	Semaxinib
Carcinoma	Angiogenesis Inhibitors
Neoplasms, Glandular and Epithelial	Angiogenesis Modulating Agents
Neoplasms by Histologic Type	Growth Substances
Neoplasms	Physiological Effects of Drugs
Kidney Neoplasms	Growth Inhibitors
Urologic Neoplasms	Antineoplastic Agents
Urogenital Neoplasms	Protein Kinase Inhibitors
Neoplasms by Site	Enzyme Inhibitors
Kidney Diseases	Molecular Mechanisms of Pharmacological Action

ClinicalTrials.gov processed this record on December 05, 2016