Trial record 1 of 1 for: NCT00019539
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Monoclonal Antibody Therapy in Treating Patients With Advanced Kidney Cancer

This study has been completed.

Sponsor:
National Cancer Institute (NCI)

Information provided by:
National Cancer Institute (NCI)

ClinicalTrials.gov Identifier:
NCT00019539

First received: January 9, 2009
Last updated: June 19, 2013
Last verified: October 2004
History of Changes

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

Purpose

RATIONALE: Monoclonal antibodies can locate tumor cells and either kill them or deliver tumor-killing substances to hem.

PURPOSE: Randomized phase II trial to determine the effec iveness of monoclonal antibody therapy in treating patients who have advanced kidney cancer that cannot be surgically removed.

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

Study Type: Interventional
Study Design: Primary Purpose: Treatment

Official Title: Phase II Randomized Study of Monoclonal Antibody VEGF in Patients With Unresectable Advanced Renal Cell Cancer

Resource links provided by NLM:

MedlinePlus related topics: Cancer

Genetic and Rare Diseases Informa ion Center resources: Kidney Cancer Renal Cancer

U.S. FDA Resources

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

Study Start Date: November 1998
Study Completion Date: November 2004

Detailed Description:

OBJECTIVES: I. Determine the effect of monoclonal antibody VEGF on time to progression, angiogenesis, and overall survival in pa ients with unresectable advanced renal cell cancer.

II. Evaluate serum antibody levels and biologically active vascular endothelial growth factor levels in the plasma of patients treated with this regimen.

III. Evaluate the toxicity of this regimen in these patients.

PROTOCOL OUTLINE: This is a randomized study. Patients are stratified by prior interleukin-2 therapy (yes vs no).

Patients are randomized to receive either placebo or one of two doses of monoclonal antibody VEGF. Following an initial loading dose, patients receive one dose of the study drug intravenously every 2 weeks for up to 2 years in the absence of disease progression. Patients who are given

placebo and experience disease progression are offered monoclonal antibody VEGF and thalidomide if there are no contraindications.

PROJECTED ACCRUAL:

A total of 150 patients will be accrued for this study over 2 years.

Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)

Criteria

PROTOCOL ENTRY CRITERIA:

--Disease Characteristics-- Histologically proven unresectable advanced renal cell cancer Measurable disease Must have received or not be a suitable candidate for interleukin-2 therapy No papillary or collecting duct renal cell cancer No CNS metastases --Prior/Concurrent Therapy-- Biologic therapy: See Disease Characteristics No prior thalidomide At least 4 weeks since other prior biologic therapy No other concurrent biologic therapy Chemotherapy: At least 4 weeks since prior chemotherapy No concurrent chemotherapy Endocrine therapy: At least 4 weeks since prior endocrine therapy No concurrent corticosteroid therapy Radiotherapy: At least 4 weeks since prior radiotherapy No concurrent radiotherapy Surgery: See Disease Characteristics --Patient Characteristics-- Age: 18 and over Performance status: ECOG 0-2 Life expectancy: At least 6 months Hematopoietic: WBC at least 1,000/mm3 Platelet count at least 75,000/mm3 No coagulation disorder, active bleeding, or wound healing problem Hepatic: Total bilirubin no greater than 2.0 mg/dL (for patients with Gilbert's disease, direct bilirubin less than 0.5 mg/dL) SGOT or SGPT no greater than 3 times normal Renal: Creatinine no greater than 2.0 mg/dL Cardiovascular: No coronary artery disease Other: Not pregnant or nursing Negative pregnancy test Fertile patients must use effective contraception No clinically evident preexisting peripheral neuropathy

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 this study by its ClinicalTrials.gov identifier: NCT00019539

Locations

United States, Maryland

Surgery Branch
Bethesda, Maryland, United States, 20892

Sponsors and Collaborators

National Cancer Institute (NCI)

Investigators

Study Chair: James Chung-Yin Yang National Cancer Institute (NCI)

More Information

ClinicalTrials.gov Identifier:	NCT00019539 History of Changes
Obsolete Identifiers:	NCT00001707
Other Study ID Numbers:	CDR0000066669 NCI-98-C-0159 NCI-T98-0035
Study First Received:	January 9, 2009
Last Updated:	June 19, 2013
Health Authority:	United States: Federal Government

Keywords provided by National Cancer Institute (NCI):

adult solid tumor
body system/site cancer
cancer
kidney tumor
kidney/urinary cancer
recurrent renal cell cancer
renal cell cancer
solid tumor
stage IV renal cell cancer
stage, renal cell cancer

Additional relevant MeSH terms:

Carcinoma, Renal Cell
Adenocarcinoma
Carcinoma
Neoplasms, Glandular and Epithelial
Neoplasms by Histologic Type
Antibodies
Antibodies, Monoclonal
Angiogenesis Inhibitors
Angiogenesis Modulating Agents
Growth Substances

Neoplasms
Kidney Neoplasms
Urologic Neoplasms
Urogenital Neoplasms
Neoplasms by Site
Kidney Diseases
Urologic Diseases
Bevacizumab
Thalidomide

Physiological Effects of Drugs
Growth Inhibitors
Antineoplastic Agents
Immunologic Factors
Immunosuppressive Agents
Leprostatic Agents
Anti-Bacterial Agents
Anti-Infective Agents

ClinicalTrials.gov processed this record on December 05, 2016