Phase II trial of Sorafenib and Capecitabine in Advanced Renal Cell Carcinoma (RCC)

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Attempt to improve the clinical outcome of patients with metastatic renal cell carcinoma. Development of more effective anti-cancer therapy for this group of patients.

Ethical review	-
Status	Recruitment stopped
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON32358

Source
ToetsingOnline

Brief title
Sorafenib and Capecitabine in Renal Cell Carcinoma

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
kidney cancer, renal cell carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Bayer

Intervention

Keyword: Chemotherapy, Multi tyrosine kinase inhibitor, Oral agents, Renal cell cancer

Outcome measures

Primary outcome

Progression free survival at 12 months

Secondary outcome

Overall remission

Overall survival

Safety

Study description

Background summary

At 12 months a percentage of 15% is expected following the use of Soraim of the study is to investigate the efficacy of the combination of standard therapy with oral Sorafenib and capecitabine (an oral cytotoxic agent) at 12 months as measured bij percentage progression free disease patients.

Paitents who are eligible for therapy with Sorafenib will be asked to particpate.

The burden for the patient is more or less equivalent to that if they receive standard therapy with Sorafnib alone. There is an additional chance of side effects related to capecitabine, i.e. decline in WBC and platelets, skin reaction, and diarrhea.

Endpoint: progression free remission at 12 months as measured according to standard methods by CT scan.

Study objective

Attempt to improve the clinical outcome of patients with metastatic renal cell carcinoma. Development of more effective anti-cancer therapy for this group of patients.

Study design

Phase II study with the combination of two drugs, both used for the treatment of metastatic renal cell carcinoma.

Intervention

Two drugs: Sorafenib and Capecitabine

Study burden and risks

Similar to that during standard therapy with Sorafenib alone

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Advanced renal cell carcinoma (metastatic RCC)

Exclusion criteria

Other types of malignancies
History of cardiac disease
Serious clinical infections
Symptomatic brain metastases

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-10-2007
Enrollment:	53
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Nexavar
Generic name:	Sorafenib
Registration:	Yes - NL intended use

Ethics review

Not available

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2007-005967-82-NL
CCMO	NL20351.058.07