A randomized, double-blind, placebo-controlled, multicenter phase III study to compare the safety and efficacy of RAD001 plus Best Supportive Care (BSC) versus BSC plus Placebo in patients with metastatic carcinoma of the kidney which has progressed on VEGF receptor tyrosine kinase inhibitor therapy.

Published: 23-11-2006
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To compare progression-free survival (PFS) in patients who receive RAD0901 plus Best Supportive Care (BSC) versus patients who receive Matching Placebo plus BSC.

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

Summary

ID

NL-OMON30372

Source
ToetsingOnline

Brief title
Fase 3 study with RAD001 in patients with renal cell carcinoma.

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym

Renal cell carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Industrie (Novartis Pharma B.V.)

Intervention

Keyword: after VEGF TKI, RAD001, renal cell carcinoma

Outcome measures

Primary outcome

To compare progression-free survival (PFS) in patients who receive RAD001 plus

BSC versus patients who receive Matching Placebo plus BSC.

Secondary outcome

To compare the overall survival for patients who received RAD001 plus BSC

versus Matching Placebo plus BSC.

To compare the objective response rate and duration in patients who receive

RAD001 plus BSC versus Matching Placebo plus BSC.

To describe the safety profile of RAD001 when compared to Placebo.

To assess disease related symptoms and overall QoL in patients treated with

RAD001 plus BSC and to compare these patients reported outcomes to the Matching

Placebo plus BSC treatment group.

To describe the pharmacokinetics of RAD001 in patients with renal cell cancer.

To explore the relationship between RAD001 blood levels and efficacy/safety

endpoints.

Study description

Background summary

Renal cell carcinoma (RCC) is expected to account for more than 35.000 new diagnoses of cancer and over 12.000 cancer deaths in the United States during 2005. In Europe, the number of new diagnoses and cancer deaths from RCC is approximately double that in the United States. In the Netherlands incidence of RCC is 1500 per year. 1/3 has metastatic disease at time of diagnosis, 1/3 will experience a relapse later on. Median survival for patients with metastatic disease is about 13 months.

RCC is characterized by a high degree of resistance to chemotherapy. Interferon Alfa and interleukin-2 are standard therapies for patients with metastatic RCC. Only a minority of treated patients experiences a favorable response. Recently developed VEGF targeted therapies have demonstrated activity in metastatic RCC.

There is no standard therapy available, once a patient's disease progresses after VEGF targeted therapies. Therefore, the identification of new agents with antitumor activity against RCC is of high priority.

Study objective

To compare progression-free survival (PFS) in patients who receive RAD0901 plus Best Supportive Care (BSC) versus patients who receive Matching Placebo plus BSC.

Study design

After screening evaluations have been performed patients are randomized to receive RAD001 plus BSC or BSC plus Matching Placebo. This part of the study is the blinded treatment phase. Patients who have disease progression may be unblinded, patients who had received placebo may be offered open-label treatment with RAD001. This treatment may be continued till progressive disease occurs. The patient will than enter the follow up phase.

Patients who have disease progression and are unblinded and had treatment with RAD001 will enter the follow up phase immediately.

Intervention

After randomisation patients will be instructed to use RAD001 10 mg daily dose or matching placebo. Tablets contain 5 mg each.

Study burden and risks

After the screeningperiod patients have to visit the hospital once in 2 weeks.
Tumor evaluation will be done once in 2 months.
Pulmonary function tests will be done during the screeningperiod.
Use of RAD001 might cause side effects.

Na de screeningsperiode zal de patiënt 1 x per 2 weken naar het ziekenhuis moeten voor controle.
Tumorcontrole zal 1 x per 2 maanden plaatsvinden.
Een longfunctietest is voor deelname in dit onderzoek nodig tijdens de screeningsperiode.
Mogelijk risico gedurende dit onderzoek zijn de bijwerkingen van RAD001.

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

Patients with metastatic carcinoma of clear cell Renal Cell Cancer (histological or cytological confirmed)
Patients must have progression on or within 6 months of stopping treatment with a VEGF receptor tyrosine kinase inhibitor
Patients with at least one measurable lesion at baseline

Exclusion criteria

Patients who have previously received mTOR inhibitors.
Patients currently receiving chemo-, immuno- or radiotherapy
Patients with an active, bleeding diathesis or on oral anti-vitamin K medication (except low dose coumadin)

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-03-2008
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Certican
Generic name:	Everolimus
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	23-11-2006
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	23-04-2007
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	EUCTR2006-002070-21-NL
CCMO	NL14496.058.06