# A single center open-label uncontrolled study to investigate tumour response and vascularization changes in neoadjuvant therapy with BAY 43-9006 single agent therapy in patients with operable renal cell cancer

Submission date	Recruitment status	[X] Prospectively registered
14/02/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
14/02/2006	Completed	Results
Last Edited	Condition category	Individual participant data
31/07/2009	Cancer	Record updated in last year

# **Plain English summary of protocol**Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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# Additional identifiers

EudraCT/CTIS number

**IRAS** number

#### ClinicalTrials.gov number

## Secondary identifying numbers

N/A

# Study information

#### Scientific Title

#### **Study objectives**

In view of good pre-clinical and clinical results, it is thought that patients with renal cell cancer will benefit from BAY 43-9006 in a neoadjuvant setting. We anticipate a benefit with the treatment of BAY 43-9006 when there is a tumour reduction more than 30%.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

## Study design

Single center open-label uncontrolled study

#### Primary study design

Interventional

# Secondary study design

Randomised controlled trial

# Study setting(s)

Hospital

# Study type(s)

Treatment

#### Participant information sheet

# Health condition(s) or problem(s) studied

Renal cell cancer

#### **Interventions**

All patients will receive BAY 43-9006 400 mg twice a day (bid) for the period of 8 weeks.

#### Intervention Type

Drug

#### **Phase**

**Not Specified** 

#### Drug/device/biological/vaccine name(s)

BAY 43-9006 [sorafenib (Nexavar®)]

#### Primary outcome measure

Parameters: tumour response and vascularization.

- 1. Tumour reduction measured by CT
- 2. Quantitative changes in perfusion as measured by means of contrast enhanced ultrasound and various image processing techniques

#### Secondary outcome measures

Parameters: toxicity.

- 1. Toxicity by means of the remaining laboratory assessments
- 2. Number and severity of adverse events (AEs)
- 3. Number and severity of serious adverse events (SAEs)

#### Overall study start date

01/03/2006

#### Completion date

01/07/2008

# **Eligibility**

## Key inclusion criteria

- 1. Patients >18 years
- 2. Eastern Cooperative Oncology Group (ECOG) = 1 (2)
- 3. Candidates for a radical or partial nephrectomy who are fit for surgery
- 4. At least one uni-dimensional measurable lesion, measured by computed tomography (CT) scan
- 5. Adequate bone marrow function
- 6. Adequate liver function
- 7. Adequate renal function
- 8. Adequate coagulation
- 9. Men and women must have adequate barrier birth control before and during and for 1 week after the trial
- 10. Signed informed consent

## Participant type(s)

Patient

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

# Target number of participants

30

#### Key exclusion criteria

- 1. History of allergic reactions attributed to compounds of similar chemical or biologic composition to BAY43- 9006
- 2. History of cardiac disease, congestive heart failure, cardiac arrhythmias requiring antiarrhythmic therapy or uncontrolled hypertension
- 3. History of chronic hepatitis B or C and HIV infection
- 4. Patients with seizure disorders (requiring medication)
- 5. Patients with evidence or history of bleeding diathesis
- 6. Other investigational drug therapy within 30 days
- 7. Women of childbearing potential with a positive pregnancy test within 7 days before start treatment
- 8. Any condition that is unstable or could jeopardize the safety of the patient and their compliance in the study
- 9. Unable to swallow oral medication
- 10. Tumour/disease specific criteria: chronic diarrhoea, bowel obstruction, degree of malnutrition, malabsorption
- 11. Major surgery within 4 weeks before screening

#### Date of first enrolment

01/03/2006

#### Date of final enrolment

01/07/2008

# Locations

#### Countries of recruitment

**Netherlands** 

1100 DD

Study participating centre
Academic Medical Center (AMC)
Amsterdam
Netherlands

Sponsor information

#### Organisation

Academic Medical Center (AMC), Department of Urology (The Netherlands)

#### Sponsor details

P.O. Box 22660 Amsterdam Netherlands 1100 DD

# Sponsor type

Not defined

#### **ROR**

https://ror.org/03t4gr691

# Funder(s)

# Funder type

Hospital/treatment centre

#### Funder Name

Academic Medical Center (AMC), Department of Urology (Netherlands)

# **Results and Publications**

## Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration