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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 anti-arrhythmic 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

Study participating centre
Academic Medical Center (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

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

Sponsor details
P.O. Box 22660
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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