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A single center open-label uncontrolled study to investigate the prostate specific antigen (PSA) and tumor vascularization response rate of neoadjuvant therapy with BAY 43-9006 single agent therapy in patients with operable prostate cancer

Submission date
08/03/2006

Recruitment status
No longer recruiting

Registration date
08/03/2006

Overall study status
Completed

Last Edited
11/08/2009

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

Protocol serial number

NTR577

Study information

Scientific Title

Study objectives
In view of good pre-clinical and clinical results, it is thought that patients with prostate 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 PSA decline of more than 25%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Primary study design
Interventional

Study design
A single center open-label uncontrolled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prostate 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)
Sorafenib (BAY 43-9006)

Primary outcome(s)
1. Response rate by means of PSA
2. Quantitative changes in perfusion as measured by means of static and dynamic contrast enhanced ultrasound and static and dynamic contrast enhanced magnetic resonance imaging (MRI)
3. Micro vessel density (MVD) in biopsy and resected material

Key secondary outcome(s)

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)

Completion date
01/07/2008

Eligibility

Key inclusion criteria
1. Patients >18 years
2. Eastern Cooperative Oncology Group (ECOG) = 1(2)
3. Biopsy proven prostate cancer
4. Candidate for a radical prostatectomy and fit for surgery
5. Clinical stage T1-T2 Nx-0 Mx-0
6. Adequate bone marrow function
7. Adequate liver function
8. Adequate renal function
9. Adequate coagulation
10. Men and partners must have adequate barrier birth control before and during and for 1 week after the trial
11. Signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Male

Key exclusion criteria
1. History of allergic reactions attributed to compounds of similar chemical or biologic composition to BAY 43-9006
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 human immunodeficiency virus (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. Any condition that is unstable or could jeopardize the safety of the patient and their compliance in the study
8. Unable to swallow oral medication

9. Tumour/disease specific criteria: chronic diarrhoea, bowel obstruction, degree of malnutrition, malabsorption
10. 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 Centre (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration