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 | Recruitment status | Prospectively registered |
|-------------------|----------------------|-----------------------------|
| 08/03/2006 | No longer recruiting | ☐ Protocol |
| Registration date | Overall study status | Statistical analysis plan |
| 08/03/2006 | Completed | Results |
| Last Edited | Condition category | Individual participant data |
| 11/08/2009 | Cancer | Record updated in last year |

Plain English summary of protocolNot provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study design

A single center open-label uncontrolled study

Primary study design

Interventional

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)
- 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 antiarrhythmic 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 summaryNot provided at time of registration