

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

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| Submission date 08/03/2006 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 08/03/2006 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 11/08/2009 | Condition category Cancer | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> 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

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

Study design

A single center open-label uncontrolled study

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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. 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

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

30

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)

Sponsor details

Department of Urology

P.O. Box 22660

Amsterdam

Netherlands
1100 DD

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (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