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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28891

Source
Nationaal Trial Register

Brief title
BAY 43-9006 before radical prostatectomy

Health condition

All patients with histological proven prostate cancer who are eligible for laparoscopic radical prostatectomy will be asked to participate in the BAY 43-9006 study.

Sponsors and support

Primary sponsor: Academic Medical Center, University of Amsterdam. Department of Urology

Intervention

Outcome measures

Primary outcome

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 MRI;
3. Micro vessel density (MVD) in biopsy and resected material.

Secondary outcome

1. Toxicity by means of the remaining laboratory assessments;
2. Number and severity of AEs;
3. Number and severity of SAEs.

Study description

Background summary

BAY 43-9006 or Sorafenib (family of the RAF kinase inhibitors) is an orally bio available anti-angiogenic drug with anti-proliferative and anti-angiogenic properties which targets the tumour and neo-vasculature. In view of good pre-clinical and clinical results, it was decided to investigate BAY 43-9006 in a translational study to monitor the effects of BAY 43-9006 in a neo-adjuvant setting and to evaluate the benefit in patients with prostate cancer in the future.

Study objective

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%.

Intervention

All patients will receive BAY 43-9006 400 mg bid for the period of 8 weeks.

Contacts

Public
Academic medical Center (AMC) Department of Urology
P.O. Box 22660

S.A. Zaaijer
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5666030
Scientific
Academic medical Center (AMC) Department of Urology
P.O. Box 22660
S.A. Zaaijer
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5666030

Eligibility criteria

Inclusion criteria

1. Patients > 18 years;
2. 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.

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 hepatits 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.;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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2006
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-01-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL533
NTR-old	NTR577
Other	: N/A
ISRCTN	ISRCTN62522358

Study results

Summary results
N/A