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.

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26901

Bron
NTR

Verkorte titel
RCC: neoadjuvant therapy with BAY 43-9006

Aandoening

All patients with renal cell cancer who are candidates for a partial or radical nephrectomy, will be asked to participate in the BAY 43-9006 study.

Ondersteuning

Primaire sponsor: Academic Medical Center, University of Amsterdam, Department of Urology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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 renal cell cancer in the future. Previous studies with BAY 43-9006 in renal cell cancer were performed in patients with advanced renal cell cancer.

Doel van het onderzoek

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%.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients > 18 years;
2. 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 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2006
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-01-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL530
NTR-old	NTR574
Ander register	: N/A
ISRCTN	ISRCTN46317673

Resultaten

Samenvatting resultaten
N/A