Angiogenesis Inhibitors and Hypertension: Clinical Aspects

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular hypertensive disorders
Study type	Observational invasive

Summary

ID

NL-OMON31245

Source
ToetsingOnline

Brief title
None

Condition

- Vascular hypertensive disorders

Synonym
high blood pressure, hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: hypertension, tyrosine kinase inhibitors, VEGF

Outcome measures

Primary outcome

- Patients developing an increase in blood pressure or not will be compared.

The patient*s blood pressure is classified according to the WHO criteria for

hypertension in stage 0, stage I, stage II and stage III.

- Patients in whom the blood pressure increases at least 10 mmHg or in whom the

blood pressure increases from one stage to the next are considered to have a

clinically relevant and treatment-induced rise in blood pressure. A subdivision

is made between patients with a one-step rise and a two-step rise in stages.

Secondary outcome

None

Study description

Background summary

Inhibition of angiogenesis with antibodies against vascular endothelial growth factor (VEGF) or VEGF receptor antagonists (tyrosine kinase inhibitors) has become an established treatment for cancer. An unanticipated side effect of angiogenesis inhibitors is the development of hypertension.
The pathogenesis of this hypertension is unknown. Not all patients will develop hypertension. However, it is not known which patient will and which patient will not develop hypertension.

Study objective

The aim of the study is:
- To find simple clinical and/or laboratory parameters to predict the development of hypertension during treatment with the tyrosine kinase inhibitor Sunitinib. If such parameters are present it will be evaluated prospectively

whether one or more of these parameters predict the development of hypertension in a second cohort of patients treated with Sunitinib.
- To elucidate the mechanism of hypertension during treatment with the tyrosine kinase inhibitor Sunitinib and therefore providing more insight in the pathogenesis of essential hypertension in the overall population.

Study design

This is a single centre, prospective, observational study. In total 80 patients intended to be treated with Sunitinib will be included. They will be asked to complete a questionnaire. During the follow-up of 10 weeks, at baseline, 4 and 10 weeks after starting treatment with Sunitinib, blood and urine samples will be collected and non-ambulatory and ambulatory blood pressure measurement will be performed. Blood pressure will be classified according to the WHO criteria for hypertension in stage 0, stage I, stage II and stage III. Demographic and laboratory parameters of the groups of patients either developing an increase in blood pressure or not will be compared. If such parameters are present it will prospectively be evaluated whether one or more of these parameters predict the development of hypertension in a second cohort of patients treated with an angiogenesis inhibitor.

Study burden and risks

The risks associated with participation are almost similar as to no participation and include the risks associated with the treatment with Sunitinib. In addition, the standard risks associated with the use of an intravenous canula must be mentioned. The 24-hour ambulatory blood pressure measurement might be considered as a burden. Non-ambulatory blood pressure measurement requires a 30 minute stay in the hospital during a routine visit at the outpatient clinic.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Men and women, with either renal cell carcinoma or gastrointestinal stromal tumors (GIST) intended to be treated solely with Sunitinib (single-agent treatment) and who are considered fit enough by their treating physician to receive Sunitinib.

Exclusion criteria

None

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2008
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Spacelabs (902017 and 902007) = ambulatory blood pressure measurement
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	SUTENT
Generic name:	Sunitinibmalate
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	14-06-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-07-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2007-002038-13-NL
CCMO	NL17495.078.07