Diarrhea during use of the oral angiogenesis inhibitors sunitinib and sorafenib

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To identify what might be the cause of the occurrence of diarrhea during the use of angiogenesis inhibitors sunitinib and sorafenib in patients with a malignancy.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON35932

Source
ToetsingOnline

Brief title
Diarrhea during use of sunitinib and sorafenib

Condition

- Other condition
- Malabsorption conditions
- Renal and urinary tract neoplasms malignant and unspecified

Synonym
diarrhea

Health condition

GIST, hepatocellulair carcinoom of medullair schildkliercarcinoom

Research involving
Human

Sponsors and support

Primary sponsor: Integraal Kankercentrum Oost
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: angiogenesis inhibitor, diarrhea, sorafenib, sunitinib

Outcome measures

Primary outcome

Descriptive: from the outcomes of laboratory investigations, H2-breath test and

scopies we hope to identify the cause of the diarrhea, e.g. secretoir,

absorption failure or inflammation.

Secondary outcome

nvt

Study description

Background summary

The recent development of angiogenesis inhibitors represents a major breakthrough in the treatment of cancer. Sunitinib (Sutent ®) and sorafenib (Nexavar ®) are two registered angiogenesis inhibitors. Sunitinib is a multiple tyrosine kinase inhibitor that is approved for the treatment of metastatic renal cell carcinoma and imatinib-resistant gastrointestinal stromal tumours (GIST).
Sorafenib is a multiple tyrosine kinase inhibitor and registered for metastatic renal cell carcinoma and for treatment of unresectable or metastatic hepatocellular carcinoma.Very recently, sorafenib has also been indicated for treatment-resistant non medullary thyroid carcinoma.
Now that both sunitinib and sorafenib are used frequently, the side effects become increasingly visible. One of the most common side effects is diarrhea. Diarrhea leads to a reduced quality of life. That is very clear in case of severe diarrhea grade 3 or 4. But long-term mild diarrhea (grade 1 or 2) also leads to a significantly decreased quality of life. Patients may become socially invalidated by the increased use of toiletfacilities or because they suffer from abdominal cramps and flatulence. Often they can not tolerate

certain foods. Besides the impact on quality of life, diarrhea may be such that dose reduction is necessary or that the therapy should be discontinued. This has an adverse effect on the antitumor efficacy of treatment and duration of progression-free survival and possibly even survival. Moreover, changes in the gastrointestinal tract lead to changes in the pharmacokinetics and - dynamics of these drugs, so the effectiveness of these drugs may be affected. The treatment and prevention of diarrhea is therefore of the utmost importance.

The exact pathophysiological mechanism of the diarrhea is so far unknown, and this hinders the development of better therapies and preventive measures. The purpose of this study is to gain more knowledge about the pathophysiological mechanism of diarrhea in patients treated with angiogenesis inhibitors sunitinib and sorafenib.

Study objective

To identify what might be the cause of the occurrence of diarrhea during the use of angiogenesis inhibitors sunitinib and sorafenib in patients with a malignancy.

Study design

This is an inventory, cross-sectional study

Study burden and risks

The burden in time for patients is about 5 hours in the hospital. Part of the tests can be combined with each other. Depending on the results of the tests, patients will be at the hospital between 3 and 5 times. The risks of the tests are low and comparable with the risks for a population of patients outside this study.

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

Patients with renal cell carcinoma, GIST, hepatocellular carcinoma or medullary thyroid carcinoma treated with sunitinib or sorafenib
Diarrhea CTC grade >= 1, generated during the use of angiogenesis inhibitor
Age >= 18 years
Signed informed consent

Exclusion criteria

Known history of relevant disorders: absorption disorders such as inflammatory bowel disease, celiac disease or lactose intolerance
Use of laxatives

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-09-2011
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	23-08-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL35610.091.11