Study on the influence of sunitinib and sorafenib on cognitive functioning a cross sectional study (UMCNONCO200901)

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To assess the influence of sunitinib and sorafenib on subjective and objective cognitive functioning in patients with metastatic renal cell cancer or a GIST, in order to get more insight in the prevalence, type and etiology of cognitive...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON32837

Source
ToetsingOnline

Brief title
Study on the influence of sunitinib and sorafenib on cognitive functioning.

Condition

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

Synonym
gastro intestinal stromacel tumor, GIST, kidney cancer

Health condition

GIST

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cognitive functioning, sorafenib, suntinib

Outcome measures

Primary outcome

it is a pure describtive study, the results of the neuropsychological tests and

the results of the lab tests of the different study groups will be compared.

Secondary outcome

not applicable

Study description

Background summary

Targeted therapy concerns the application of a new class of drugs that are specifically directed against one or more well-defined molecular targets that are relevant for carcinogenesis, cell cycle regulation, tumour progression, metastasis, tumour angiogenesis and/or apoptosis. Today, the most successful drugs in this class are directed against the vascular endothelial growth factor (VEGF) and the epidermal growth factor receptor (EGFR).
The toxicity profile of targeted therapies is still partly unknown, and the aetiology of many known side effects has not been clarified. Given the impact of side effects on the quality of life of a patient, increased knowledge on this topic is urgently required. At the moment, three targeted therapies that are directed against VEGF are registered and used in the Netherlands: Sunitinib (Sutent®) and Sorafenib (Nexavar ®) both oral tyrosine kinase inhibitors (TKIs) drugs and Bevacizumab (Avastin®), an intravenously antibody to the VEGF.
In this study we will focus on subjective and objective cognitive dysfunctioning in patients with metastatic cancer, treated with sunitinib or sorafenib. In our own clinical practice a substantial part of our patients that

are treated with targeted therapies directed against VEGF, mention that they have problems with concentrating and that their memory function is decreased. Relatives sometimes point out that the behaviour of the patient is slightly different than before starting the VEGF inhibition. Pre-clinically studies show that VEGF influences growth and recovery of neurons.

Study objective

To assess the influence of sunitinib and sorafenib on subjective and objective cognitive functioning in patients with metastatic renal cell cancer or a GIST, in order to get more insight in the prevalence, type and etiology of cognitive dysfunctioning during treatment with sunitinib or sorafenib.

Research questions:
•What is the prevalence of subjective and objective cognitive dysfunctioning during treatment with sunitinib or sorafenib?
•What is the type of cognitive dysfunctioning during treatment with sunitinib or sorafenib?
•What is the possible mechanism of sunitinib or sorafenib related cognitive dysfunctioning, and is it related to special areas in the brains?
•Is cognitive dysfunctioning associated with demographic, psychological and /or physical variables?
•Is cognitive dysfunctioning associated with fatigue or mood disorders?
•Is there a relation between VEGF level in blood and the presence of cognitive dysfunctioning during treatment with sunitinib or sorafenib?
•Is there a relation between cytokine levels and the presence of cognitive dysfunctioning during treatment with sunitinib or sorafenib?

Study design

The study design is a cross sectional explorative study with a healthy control group and a control group patients with metastastic disease but no treatment yet.

Study burden and risks

For patients it will take 2 hours. In these 2 hours different neuropsychological tests will be done, which require concentration the tests are furthermore not aggravating. Also some blood will be taken one time. Besides a small change of a haematoma there are no further risks.

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:
-patients with metastastic renal cell cancer or GIST who are on treatment with Sunitinib or Sorafenib for >= 8 weeks
- Karnofsky score > 70%
- age > 18 year.
- written informed consent for study;Healthy controls selection:
-Healthy individuals:
- Karnofsky score > 70%
- age > 18 year
- written informed consent for study;Patient controls selection
Inclusion criteria:
-patients with metastastic renal cell cancer or GIST who aren*t treated yet (only interferon alfa or interleukine 2 treatment is allowed when > 12 months ago.
- Karnofsky score > 70%
- age > 18 year.

- written informed consent for study

Exclusion criteria

- contra-indications for treatment with Sunitinib or Sorafenib
- patients who do not speak or write the Dutch language adequately
- known brain metastasis
- use of psychiatric or anti-epileptic medication
- known cognitive disorders unrelated to diagnosis or medication use
- radiotherapy on the brain at any time in the past
- systemic chemotherapy
- in the last 12 months interferon alfa or interleukine-2 treatment
- operation in the last 6 months
- Diabetes Mellitus
- Stroke/TIA;Healthy controls section:
- individuals who do not speak or write the Dutch language adequately
- use of psychiatric or anti-epileptic medication
- known cognitive disorders (Alzheimer e.g.)
- radiotherapy on the brain at any time in the past
- systemic chemotherapy
- operation in the last 6 months
- Diabetes Mellitus
- stroke/TIA;Patient controls section:
- patients who do not speak or write the Dutch language adequately
- known brain metastasis
- use of psychiatric or anti-epileptic medication
- known cognitive disorders unrelated to diagnosis or medication use
- radiotherapy on the brain at any time in the past
- systemic chemotherapy
- in the last 12 months interferon alfa or interleukine-2 treatment
- operation in the last 6 months
- Diabetes Mellitus
- stroke/TIA

Study design

Design

Study phase:	4
Study type:	Observational invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	80
Type:	Anticipated

Ethics review

Not approved

Date:	31-03-2009
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	NL26369.091.08