Evaluation of cognitive function of patients treated with sunitinib or sorafenib (UMCONCO200904

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Tot evaluate the cognitive function of patients treated with sunitinib or sorafenib for metastatic renal cell cancer or a GIST, in order to get more insight in the prevalence, typeand etiology of cognitive dysfunctioning during treatment with...

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

Summary

ID

NL-OMON33283

Source
ToetsingOnline

Brief title
Evaluation of cognitive function of patients with sunitinib or sorafenib

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

Tot evaluate the cognitive function of patients treated with sunitinib or sorafenib for 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 an explorative pilot 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

Patients:
- 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:	Recruiting
Start date (anticipated):	24-07-2009
Enrollment:	80
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	19-06-2009
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	NL28333.091.09