SNIPP study - A investigator initiated phase II study of sunitinib in patients with recurrent paraganglioma/pheochromocytoma

Published: 12-09-2011
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To investigate if sunitinib has clinical significant activity in patients with metastatic/recurrent paraganglioma/pheochromocytoma.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Endocrine and glandular disorders NEC
Study type	Interventional

Summary

ID

NL-OMON37490

Source
ToetsingOnline

Brief title
SNIPP study

Condition

- Endocrine and glandular disorders NEC
- Endocrine neoplasms malignant and unspecified

Synonym
paraganglioma - tumors of neuroendocrine tissue

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Pfizer

Intervention

Keyword: malignancy, paraganglioma, pheochromocytoma, sunitinib

Outcome measures

Primary outcome

The primary endpoint is the clinical benefit rate, defined as either a partial

response, complete response or stable disease for at least 12 weeks.

Secondary outcome

Secondary endpoints are:

- biochemical response

- overall survival

- time to progression

- overall response rate (partial response + complete response)

- tumor symptom improvement

Study description

Background summary

Paragangliomas are highly vascularized tumors that arise from the parasympathetic system and the adrenal medulla (pheochromocytoma) and can produce catecholamines. A subset of these tumors are characterized by pseudohypoxia: in tumor cells survival strategies for hypoxic conditions are activated resulting among others in production of vascular endothelial growth factor (VEGF) which induces angiogenesis.
The primary treatment of paraganglioma/pheochromocytoma is surgical resection. However, some are malignant and metastasize. The 5-year survival for patients with metastatic paraganglioma is less than 50%. In case of metastatic disease it is recommende to perform debulking surgery is 80-90 % of the tumor bulk can be safely excised, however no survival benefit has been demonstrated. Chemotherapy can induce tumor responses of short dureation at the cost of

significant toxicity and is not routine practice in the Netherlands for paraganglioma. Treatment with radioactive MIBG is offered to patients in the Netherlands but it is not widely available and neither the optimal dose and schedule as the influence on prognosis has been determined. Sunitinib is a multi targeted tyrosine kinase inhibitor, blocking amogst others the VEGF pathway. Sunitinib is standard first line treatment for patients with metastatic renal cell carcinoma which is also characterized by pseudo-hypoxia. Tumor response on sunitinib have been desrcinbed in patients with advanced and metastatic paraganglioma.

Study objective

To investigate if sunitinib has clinical significant activity in patients with metastatic/recurrent paraganglioma/pheochromocytoma.

Study design

Non-randomized, non-blinded phase II study of sunitinib in patients with advanced or metastatic recurrent paraganglioma or pheochromocytoma.

Intervention

Sunitinib 50 mg will be administered orrally daily for 4 weeks out of every 6 weeks.

Study burden and risks

Patients can experience side effects of sunitinib, the most frequent are: hypertension, fatigue, gastroinestinal symptoms and skin discoloration. Patients have to visit the outpatient clinic once every 6 weeks, then blood will be drawn and urinalaysis will be performed. After every 2 cycles response will be assessed with a CT scan. Patients will be given a a blood pressure device and will be asked to measure and write down their blood pressure weekly during the first cycle and once every 2 weeks thereafter. Patients have to write down intake of study mediation in a diary.
For patients who consent to a tumor biopsy, this will be performed after 2 treatment cycles. Patients who do not want a biopsy can participate to the 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

- metastatic or locally recurrent paraganglioma or pheochromocytoma not amenable to curative treatment modalities
- measurable disease
- ECOG performance status 0-2
- at least 28 days since proior radiation or major surgery
- able to take oral medicatio- able to stop prohibited selected CYP3A4 inhibitors

Exclusion criteria

- prior therapy with antiangiogenic agents or multitargeted tyrosine kinase inhibitors
- known brain metastasis
- serious medical conditions or cardiac disease
- uncontrolled hypertension
- other concurrent anticancer treatment

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-07-2012
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	sunitinib malate
Generic name:	sunitinib
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	12-09-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-06-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-09-2013

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-02-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-09-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2011-003163-29-NL
ClinicalTrials.gov	NCT00843037
CCMO	NL37777.042.11