

# 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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Endocrine and glandular disorders NEC
<b>Study type</b>	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 recommended to perform debulking surgery if 80-90 % of the tumor bulk can be safely excised, however no survival benefit has been demonstrated. Chemotherapy can induce tumor responses of short duration 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 amongst 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 described 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 orally 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, gastrointestinal symptoms and skin discoloration. Patients have to visit the outpatient clinic once every 6 weeks, then blood will be drawn and urinalysis will be performed. After every 2 cycles response will be assessed with a CT scan. Patients will be given 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 medication 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**

### **Public**

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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 prior radiation or major surgery
- able to take oral medication- 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