# Phase II study of sunitinib (SU011248) in patients with small cell lung cancer who are either chemo-naïve (extensive disease) or have a "sensitive" relapse

Published: 16-03-2009
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To assess the therapeutic activity of SU11248 in patients with exptensive disease small cell lung cancer who are either chemonaive or have a sensitive relapse

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Respiratory and mediastinal neoplasms malignant and unspecified |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON33984

**Source**
ToetsingOnline

**Brief title**
EORTC 08061

### Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms

**Synonym**
small cell lung cancer

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** European Organisation for Research in Treatment of Cancer (EORTC)

**Source(s) of monetary or material Support:** EORTC

## Intervention

**Keyword:** Phase II, SCLC ED, SU11248

## Outcome measures

### Primary outcome

Disease control rate (number of CR+PR+SD) at 4 weeks

### Secondary outcome

Response rate

Duration of progression free survival

Duration of response

Duration of survival

Toxicity

# Study description

### Background summary

Result of clinical management of patients with extensive disease small cell lung cancer remains far from satisfactory since median survival is approximately 9 months and virtually all patients die of disease despite all efforts. The only way in the short term to improve upon these results is to incorporate agents with different mechanisms of action into exisiting combinations. It is widely demonstrated that neo-angiogenesis and its mediators represent useful indicators of poor prognosis in SCLC. Therefore, interfering with neo-angiogenesis is of potential interest in this malignancy. The novel agent SU11248simultaneously inhibits KIT, PDGFR, along with VEGFR and FLT3 kinases, all being interested targets in SCLC.

### Study objective

To assess the therapeutic activity of SU11248 in patients with exptensive disease small cell lung cancer who are either chemonaive or have a sensitive

relapse

### Study design

Open label non randomized multicentre phase II trial, single arm with Fleming one stage design

### Intervention

Orally administered SU11248 loading dose 150 mg followed by 37.5 mg/day continuously

### Study burden and risks

Usuaul risks associated with treatment with cytotoxic therapy. In addition, PET scans will be performed to assess biological activity of the compound. In consenting patients a bronchoscopy will be performed after 8 weeks of treatment to assess effects of treatment in biopsy material and broncho-alveolar lavage.

## 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

Histologically proven SCLC
Chemo naive or sensitive relapse
Measurable disease
Normal organ function

## Exclusion criteria

Myocardal infarction, unstable angina, congestive heart failure, cerobrovascular accident or pulmonary embolus within 6 months
NCICTCAE grade 3 hemorrhage within 4 weeks

# Study design

## Design

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-02-2009 |
| Enrollment: | 20 |
| Type: | Anticipated |

### Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Sutent |
| Generic name: | Sunitinib |
| Registration: | Yes - NL outside intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 16-03-2009 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 29-04-2010 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

## 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 | EUCTR2006-002485-19-NL |
| CCMO | NL21019.029.09 |