A phase III randomized, double-blind study of sunitinib (SU011248, sutent) versus placebo in patients with progressive advanced/ metastatic well-differentiated pancreatic islet cell tumors

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To compare the progression-free survival (PFS) in subjects with pancreatic islet cell tumors treated with sunitinib at a starting dose of 37.5 mg daily (continuous dosing) with those treated with placebo.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Endocrine neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON30440

Source
ToetsingOnline

Brief title
N.A.

Condition

- Endocrine neoplasms malignant and unspecified

Synonym
cancer, neuro endocine tumor

Research involving
Human

Sponsors and support

Primary sponsor: Pfizer
Source(s) of monetary or material Support: Pfizer

Intervention

Keyword: double-blind, pancreatic islet cell tumors, placebo, sunitinib

Outcome measures

Primary outcome

Progression-free Survival (PFS)

Secondary outcome

- overall survival (OS)

- objective response (OR)

- duration of response (DR)

- time to tumor response (TTR)

- safety and tolerability

- patient reported outcomes (PRO)

Study description

Background summary

For patients with neuroendocrine tumors there are little proven treatments available. Besides the medicine Streptozocin there are no medicines registered for patients with pancreatic islet cell tumors.
Previously performed phase 1 and 2 studies with this patient population indicate that sunitinib could be a valuable treatment option for these patients. These studies also showed that the safety and efficacy balalance was best at 37,5 mg.

Study objective

To compare the progression-free survival (PFS) in subjects with pancreatic

islet cell tumors treated with sunitinib at a starting dose of 37.5 mg daily (continuous dosing) with those treated with placebo.

Study design

This is a multi-center double-blind randomized phase 3 study with sunitinib versus placebo in patients with pancreatic islet cell tumors. The patients will be screened at least 21 days before the treatment with study medication. During the screening several tests will be done. Thereafter the patients are in the treatment phase. In this phase patients will be randomized 1:1 in sunitinib- or placebo-group. The patients will then visit the hospital once every 4 weeks. Patients will be treated until death or progression or final analysis (endpoints).
Patients will be followed-up till 5 years or death once every 8 weeks via telephone for their 'survival follow-up'.

Intervention

Sunitinib 37.5 mg (can be adjusted to 25 mg or 50 mg) or placebo, daily for 1 year.

Study burden and risks

Patients will undergo several tests like physical examination, CT-scan chest, abdomen, pelvis, bone and brain, bloodsample, ECG, MUGA/ECG. Also questionaaires will have to be completed by the patient before any intervention on each visit (1 x per 4 weeks).

The most common side effects from sunitinib are fatigue, weakness, nausea and diarrhea.
Taking a bloodsample can cause inconvienience, pain, a little hematoma or swelling on the location of sampling.

Contacts

Public
Pfizer

Rivium Westlaan 142
2909 LD Capelle a/d IJssel
NL
Scientific
Pfizer

Rivium Westlaan 142
2909 LD Capelle a/d IJssel
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Proven diagnosis of well-differentiated pancreatic islet cell tumor.
- Locally-advanced or metatstic disease as having shown progression on a scan.

Exclusion criteria

- Poorly-differentiated pancreatic neuro endocrine tumors

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	sunitinib malate
Generic name:	SU011248
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	22-02-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-04-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-08-2007
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	EUCTR2006-004022-87-NL
CCMO	NL16280.042.07