A randomized double-blind phase III study of RAD001 10 mg/d plus best supportive care versus placebo plus best supportive care in the treatment of patients with advanced pancreatic neuroendocrine tumor (NET)

Published: 26-07-2007
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To determine whether treatment with RAD001 10 mg/d plus best supportive care prolongs the progression free survival (PFS) compared to treatment with Placebo plus best supportive care in patients with advanced pancreatic neuroendocrine tumor.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neoplastic and ectopic endocrinopathies
Study type	Interventional

Summary

ID

NL-OMON30904

Source
ToetsingOnline

Brief title
Phase 3 study in advanced pancreatic NET with RAD001

Condition

- Neoplastic and ectopic endocrinopathies

Synonym
advanced pancreatic neuroendocrine tumor

Research involving

Human

Sponsors and support

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

Intervention

Keyword: best supportive care, pancreatic NET, phase III, RAD001

Outcome measures

Primary outcome

Progression Free Survival

Secondary outcome

Objective Response Rate and Response Duration, Overall Survival, safety and tolerability of RAD001, pharmacokinetics of RAD001, tumormarkers, angiogenesis biomarkers, immunohistochemical and genetic mTOR pathway characterization on pre-treatment tumor material.

Study description

Background summary

The treatment options for unresectable or metastatic panreatic NET patients are limited.
In this cancer, the mTOR signal transduction pathway is activated in response to signaling by the insulin-like growth factor 1 (IGF-1). Interruption of this pathway by RAD001 could slow douwn tumor growth or could diminish tumor size. Earlier phase 1 and 2, and ongoing phase 2 studies show promising results.

Study objective

To determine whether treatment with RAD001 10 mg/d plus best supportive care prolongs the progression free survival (PFS) compared to treatment with Placebo plus best supportive care in patients with advanced pancreatic neuroendocrine

tumor.

Study design

Multicenter, randomized, placebo controlled, double blind, phase 3 study with RAD001 in patients with advanced pancreatic NET; best supportive care as background treatment.

Intervention

RAD001 or placebo.

Study burden and risks

Toxicity of RAD001.
Radiation exposure of CT-scans.

Contacts

Public
Novartis

Raapopseweg 1
6824 DP Arnhem
NL
Scientific
Novartis

Raapopseweg 1
6824 DP Arnhem
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients must have advanced (unresectable or metastatic) biopsy-proven pancreatic NET
- Patients must have confirmed low-grade or intermediate-grade neuroendocrine carcinoma
- Patients must have radiological documentation of progression of disease within 12 months prior to randomization. If patient received anti-tumor therapy during the past 12 months, he/she must have radiological documentation of progression of disease while on or after receiving the therapy
- Measurable disease per RECIST criteria.
- Adequate bone marrow, liver and renal function.
- Fasting serum cholesterol * 300 mg/dL OR * 7.75 mmol/L AND fasting triglycerides * 2.5 x ULN.

Exclusion criteria

- Patients with poorly differentiated neuroendocrine carcinoma, high-grade neuroendocrine carcinoma, adenocarcinoid, goblet cell carcinoid and small cell carcinoma.
- Cytotoxic chemotherapy, immunotherapy or radiotherapy within 4 weeks prior to randomization.
- Hepatic artery embolization within the last 6 months (1 month if there are other sites of measurable disease), or cryoablation/ radiofrequency ablation of hepatic metastasis within 2 months of enrollment.
- Prior therapy with mTOR inhibitors (sirolimus, temsirolimus, everolimus).
- Uncontrolled diabetes mellitus.
- Patients who have any severe and/or uncontrolled medical conditions.
- Patients receiving chronic treatment with corticosteroids or another immunosuppressive agent.
- Patients with a known history of HIV seropositivity.

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:	Recruitment stopped
Start date (anticipated):	30-07-2007
Enrollment:	2
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Certican
Generic name:	everolimus
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	26-07-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-10-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-03-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-04-2012
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	EUCTR2006-006819-75-NL
CCMO	NL18207.042.07