An open-label, multi-center everolimus roll-over protocol for patients who have completed a previous Novartis-sponsored everolimus study and are judged by the investigator to benefit from continued everolimus treatment

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Primary: To allow continued use of everolimus to patients receiving everolimus in a Novartis-sponsoredstudy which has reached its objectives and who are benefitting from treatment with everolimus as defined in the parent protocolSecondary: To...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Endocrine neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON38738

Source
ToetsingOnline

Brief title
Everolimus roll-over protocol (CRAD001C2X01B)

Condition

- Endocrine neoplasms malignant and unspecified

Synonym
advanced carcinoid

Research involving

Human

Sponsors and support

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

Intervention

Keyword: carcinoid, everolimus, roll-over protocol, sandostatin LAR

Outcome measures

Primary outcome

Number of patients receiving everolimus

Secondary outcome

Number of patients receiving everolimus

Study description

Background summary

The purpose of this study is to allow continued use of everolimus in patients who are currently receiving everolimus treatment in a Novartis-sponsored, study that has reached its study objectives, are not progressing on the current study treatment as defined by the parent protocol and are unable to access everolimus treatment outside of a clinical study. The roll-over study is designed to accept patients with varied disease origins. If patients are receiving treatment of everolimus in combination with other approved therapies, they can participate in the roll-over study, but it is not intended for combination with unapproved or experimental treatments.

Study objective

Primary: To allow continued use of everolimus to patients receiving everolimus in a Novartis-sponsored
study which has reached its objectives and who are benefitting from treatment with everolimus as defined in the parent protocol

Secondary: To collect long term data on serious adverse events.

Study design

This is a multi-center, open label study to provide continued supply of everolimus to patients currently being treated in a Novartis-sponsored Oncology CD & MA study, who are not progressing on the current study treatment as defined by the parent protocol and are unable to
access everolimus treatment outside of a clinical study. Parent studies eligible to participate in the roll-over study will be decided by Novartis. Investigator initiated trials (IIT) will not be included.
There will be no screening period for this study. Patients must return to the study center at least on a yearly basis (± 3 months) for resupply of study medication. Limited drug dispensing information will be collected.
Study medication dispensed will be recorded on the dose administration page. Reported serious adverse events will be collected continuously throughout the study in the safety database.
Patients entering the roll-over protocol should be followed at the investigator*s discretion for known or clinically notable adverse events that occur on everolimus treatment as described in the current version of the IB.
The study is expected to remain open for 10 years or until such time that enrolled patients no longer need treatment with everolimus or are able to obtain commercial supply according to local regulations for their medical condition.

Intervention

Everolimus oral daily dose 5mg BID
Sandostatin LAR (once every 4 weeks) 30mg intramuscular injection

Study burden and risks

Side effects of everolimus and Sandostatin LAR.

Contacts

Public
Novartis

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Scientific
Novartis

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1.Patient is currently enrolled in a Novartis-sponsored study receiving everolimus or everolimus plus Sandostatin LAR® and has fulfilled all their requirements in the parent study.
2.Patient is currently benefiting from the treatment with everolimus, as determined by the guidelines of the parent protocol.
3. Patient has demonstrated compliance, as assessed by the investigator, with the parent study protocol requirements.;Other protocol defined inclusion criteria may apply

Exclusion criteria

1.Patient has been permanently discontinued from everolimus study treatment in the parent study.
2.Patient is receiving everolimus in combination with unapproved or experimental treatments.;Other protocol defined exclusion criteria may apply.

Study design

Design

Study phase:	4
Study type:	Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-05-2013
Enrollment:	1
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Afinitor
Generic name:	everolimus
Product type:	Medicine
Brand name:	Sandostatin LAR
Generic name:	octreotide depot
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	21-03-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-05-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-05-2013
Application type:	First submission
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	EUCTR2012-004707-12-NL
ClinicalTrials.gov	NCT01789281
CCMO	NL43866.042.13