A single arm open label multicentre extension study of bevacizumab in patients with solid tumours on study treatment with bevacizumab at the end of a F. Hoffmann-La Roche and/or Genentech sponsored study.

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To provide continued bevacizumab therapy as single agent or in combination with an anti-cancer drug to patients with cancer, who were previously enrolled in a F. Hoffmann-La Roche (Roche)/ Genentech sponsored bevacizumab study (i.e. the Parent, P-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON37844

Source
ToetsingOnline

Brief title
Extension study of Avastin in patients on study treatment with bevacizumab.

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
cancer, Solid tumor

Research involving

Human

Sponsors and support

Primary sponsor: Roche Nederland B.V.
Source(s) of monetary or material Support: Roche Nederland B.V.

Intervention

Keyword: Bevacizumab, Solid tumours

Outcome measures

Primary outcome

To provide continued bevacizumab therapy as single agent or in combination with an anti-cancer drug to patients with cancer who were previously enrolled in a Roche/Genentech - sponsored bevacizumab P-trial and who derived benefit from the therapy administered in the P-trial To collect safety data with regard to long-term administration of bevacizumab.

Secondary outcome

To link data with the appropriate P-trial database to analyse scientific questions of interest. Details will be described in the statistical analysis plan (SAP).

Study description

Background summary

Bevacizumab is usually given until progression of the underlying cancer unless patients withdraw consent or experiences toxicities that lead to discontinuation. The time to progression is very variable from patient to patient.

Trials need to have a defined end. This is often event driven for comparative trials looking into PFS or OS. Single-arm trials often end after a prespecified

time after last patient first visit. At their completion or closure some patients might still be on treatment with bevacizumab and benefit from the continuation of the therapy with bevacizumab as their cancer has not progressed. Roche/Genentech had committed to provide treatment for above mentioned patients in the P-trial. This was also to ensure that all patients have the chance to receive similar treatment enrolled in the same trial (i.e. the first patient enrolled in a trial can benefit during enrolment and follow-up phase of a trial, where as the last
patient enrolled in a trial can benefit during follow-up phase and in this E-trial).

All eligible patients from qualifying bevacizumab P-trials can be enrolled in this E-trial, ensuring those patients have access to bevacizumab and their safety is monitored adequately.

Study objective

To provide continued bevacizumab therapy as single agent or in combination with an anti-cancer drug to patients with cancer, who were previously enrolled in a F. Hoffmann-La Roche (Roche)/ Genentech sponsored bevacizumab study (i.e. the Parent, P-trial) and who
derived benefit from the therapy administered in the P-trial. To collect safety data with regard to long-term administration of bevacizumab.

Study design

Multicenter, open-label, single-arm phase IV trial. Patients on bevacizumab at P-trial end will be enrolled immediately thereafter. Patients will receive treatment with bevacizumab as during their P-trial until progression of disease, unacceptable toxicity, withdrawal of consent or death (whichever occurs first).

Intervention

Not applicable

Study burden and risks

The MO25757 E-trial is designed to ensure an optimal risk/benefit ratio. (See protocol section 1.3)

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

1. Written informed consent prior to any study-specific procedure.;2. Patient is treated with bevacizumab at the end of the Roche/Genentech sponsored P-trial and continues to have benefit as judged by the investigator;3. Eligible for continuation of bevacizumab treatment at the end of the Parent-trial, according to Parent-trial protocol;4. Able to comply with the Extension-trial protocol MO25757;5. Female patients should not be pregnant or breastfeeding.;6. Female patients of childbearing potential/fertile male patients must use a highly effective contraceptive method during the Extension-trial and for a period of at least 6 months following the last administration of Extension-trial drug(s).

Exclusion criteria

1. Evidence of disease progression assessed according to Parent-trial protocol during the screening phase for this Extension-trial;2. Evidence of any adverse event potentially attributable to bevacizumab, for which the local label recommends permanent discontinuation.;3. A treatment interruption with bevacizumab of more than 42 days since

the last administration of bevacizumab in the Parent-trial.;4. Evidence of any other disease, neurological or metabolic dysfunction, physical examination finding or laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of the investigational drug(s) or puts the patient at high risk for treatment-related complications.

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):	02-10-2012
Enrollment:	5
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Alimta
Generic name:	Pemetrexed
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Avastin
Generic name:	Bevacizumab
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Roferon-A
Generic name:	Interferon alfa-2a

Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	21-05-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	31-07-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-09-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-02-2013
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-06-2013
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-01-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-01-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2011-002009-31-NL
CCMO	NL40453.091.12