A Randomized, Multicenter, Open-label, Phase 3 Study to Compare the Efficacy and Safety of Panitumumab and Cetuximab in Subjects with Previously Treated, Wild-type KRAS, Metastatic Colorectal Cancer

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The purpose of this clinical research study is to compare the effect of panitumumab to cetuximab (Erbitux®) in treating metastatic colorectal cancer in patients whose tumor contains the wild-type (unchanged) KRAS gene and who have previously been...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON36817

Source
ToetsingOnline

Brief title
Panitumumab & Cetuximab Wild-type KRAS, Metastatic Colorectal Cancer

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Metastases

Synonym
intestinal cancer, metstatic colorectal cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cetuximab, Compare, Metastatic Colorectal Cancer, Panitumumab

Outcome measures

Primary outcome

The primary objective is to compare the effect of panitumumab versus cetuximab

on

overall survival (OS) for chemorefractory mCRC among subjects with wild-type

KRAS

tumors.

Secondary outcome

Secondary objectives are to compare the treatment effect of panitumumab versus

cetuximab as treatment for chemorefractory mCRC among subjects with wild-type

KRAS

tumors:

• Efficacy: progression-free survival (PFS), objective response rate (ORR),

time to

response, time to treatment failure, duration of response

• Safety: subject incidence of AEs, significant laboratory changes, and

immunogenicity

• Patient Reported Outcomes (PRO)

Study description

Background summary

In this study, the study medication Panitumumab is evaluated for the treatment of patients with metastatic colorectal cancer in compare to Cetuximab. Panitumumab is a manufactured antibody. Antibodies are proteins that can be found circulating in your blood stream. The growth of metastatic colorectal cancer may be affected by the interaction of a growth factor known as *epidermal growth factor* (EGF) with its receptor. Panitumumab is an antibody directed against the receptor for EGF and has been shown to turn off the activity of the receptor and to stop the growth of cancer cells in several laboratory tests. If the same effect is observed in people that receive panitumumab as a treatment, it is possible that their cancer will improve or resolve.
Panitumumab (marketed as Vectibix®) has been approved in the United States by the Food and Drug Administration for the treatment of patients with colorectal cancer whose tumor contains EGF receptors and whose cancer has worsened while receiving or after receiving treatment with standard chemotherapy.
Panitumumab has been approved by regulatory agencies in Europe, Canada, Switzerland, and Australia for the treatment of patients with metastatic colorectal cancer whose tumor status is wild-type KRAS, contains EGF receptors, and whose cancer has worsened while receiving or after receiving treatment with standard chemotherapy.
Even though panitumumab has been approved by regulatory agencies, it is considered experimental in this study.
Approximately 250 centers will participate in this study from North America, Europe, Asia, and South America. If needed, sites in other countries may also participate.
Approximately 1000 subjects will be enrolled.

Study objective

The purpose of this clinical research study is to compare the effect of panitumumab to cetuximab (Erbitux®) in treating metastatic colorectal cancer in patients whose tumor contains the wild-type (unchanged) KRAS gene and who have previously been treated. This study is also designed to collect more information about the safety of these two drugs.

Study design

The study consists of a screening period, a treatment period, a safety

follow-up visit and a long-term follow-up period.
If you are suitable, the treatment visits will then take place once every week or bi-weekly., depending on the treatment you receive. These visits will be continued until your disease progresses, after which a safety follow-up visit will take place. After completion of the treatment your doctor will continue to monitor your disease by means of a three-monthly visit (or contact by telephone), until completion of the entire study (approximately 4 years).

You will be selected at random to receive panitumumab or cetuximab. Your changes of receiving Panitumumab are the same as your changes of receiving cetuximab.

Intervention

• Completion of 3 questionnaires related to overall health
• (previously obtained) tumor tissue for KRAS testing
• Infusion of assigned study drugs (cetuximab/panitumumab 1:1). The infusions will be given through an IV line. Each infusion will take about 30-120 minutes or more.

Study burden and risks

• Review of medical history
• Vital signs (blood pressure, pulse, respiration rate, temperature)
• Physical exam including height, weight, and physical status
• Electrocardiogram (ECG).
• Completion of 3 questionnaires related to overall health
• Review of current symptoms and medications
• (previously obtained) tumor tissue for KRAS testing
• Different blood samples will be collected
• CT or MRI scan of chest, abdomen, and pelvis
• Infusion of assigned study drugs (cetuximab/panitumumab 1:1). The infusions will be given through an IV line. Each infusion will take about 30-120 minutes or more.

Contacts

Public
Amgen

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4817 ZK Breda
Nederland
Scientific

Amgen

Minervum 7061
4817 ZK Breda
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Metastatic disease adenocarcinoma of the colon or rectum
Wild-type KRAS tumor status
ECOG performance status of 0, 1 or 2
Must have failed a prior regimen containing irinotecan and oxaliplatin for metastatic disease; Oxaliplatin and irinotecan (sequentially or in combination).
Must have previously received a thymidylate synthase inhibitor (e.g. fluorouracil, capecitabine, raltitrexed, or fluorouracil-uracil) at any point for treatment of CRC
Man or woman >= 18 years of age

Exclusion criteria

Symptomatic brain metastases requiring treatment
History of other malignancy
Prior anti-EGFr antibody therapy

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	erbitux
Generic name:	cetuximab
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	vectibix
Generic name:	panitumumab
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	15-01-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-11-2010

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-04-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-08-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2009-010715-32-NL
ClinicalTrials.gov	NCT0100137
CCMO	NL29559.040.10