A Phase 1 Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Efficacy of AMG 211 Administered as Continuous Intravenous Infusion in Subjects with Relapsed/Refractory Gastrointestinal Adenocarcinoma

Published: 27-05-2014
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Evaluate the safety and tolerability of AMG 211 in subjects with advanced gastrointestinal (GI) adenocarcinomas Determine the maximum tolerated dose (MTD) and/or biologically active dose

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON44202

Source
ToetsingOnline

Brief title
Phase 1 with AMG 211 in subjects with Gastrointestinal Adenocarcinoma

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Gastrointestinal cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: AMG 211, Phase 1, Relapsed/Refractory Gastrointestinal Adenocarcinoma

Outcome measures

Primary outcome

Determinde the safety and tolerability of AMG 211;

Determine the MTD and or biologically active dose.

Secondary outcome

Describe the pharmacokinetics (PK) of AMG 211

Determine the formation of anti-AMG 211 antibodies

Evaluate the anti-tumor activity of AMG 211

Study description

Background summary

In this study AMG 211 is studied. The safety, tolerability and efficacy are evaluated in subjects with gastrointestinal adenocarcinoma. The pharmacokinetics and pharmacodynamics are also being evaluated in this patient population.
AMG 211 is considered as an experimental drug. AMG 211 is not approved by any regulatory organization to treat any type of cancer.
About 78 patients will participate in this study in Germany and The Netherlands. Amgen Inc. is funding this clinical study.

Study objective

Evaluate the safety and tolerability of AMG 211 in subjects with advanced

gastrointestinal (GI) adenocarcinomas
Determine the maximum tolerated dose (MTD) and/or biologically active dose

Study design

This phase 1 study is performed in several hospitals. The Netherlands will participate with 2 hospitals and Germany will participate with 3 hospitals. Patients start the study after signing the informed consent. When the patient is eligible the patient starts with the treatment phase (for about 4 months). About four weeks after the end of treatment with AMG 211 the End of Study visit will be performed.
Patients will receive an increasing dose/ increasing treatment period per cohort. By doing this we want to determinde the MTD. The expansion phase will begin when the MTD is known.

Intervention

Patients will receive diverse doses of AMG 211 with diverse treatment durations. The dose and schema in the expansionphase is dependent on the MTD that is determined in the first part of the study.

Study burden and risks

Risk:
Adverse events of the study medication AMG 211. During the visits to th hospital the subjects will be monitored for adverse events.

Burden:
Study duratuon is about 6 months. The duration of each visit will be about 5 hours,

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

Male or Female >/<= 18 years old;
Pathologically documented, diagnosed GI adenocarcinoma;
At least 1 measurable tumor lesion per mirRC.;Voor een volledig overzicht van alle inclusie criteria verwijs ik u naar paragraaf 4.1 van het 20130354 protocol.

Exclusion criteria

History of allergy or reaction to any component of the AMG 211 formulation;
Active infection or prior use of IV antibiotics for treatment of infection within 2 weeks prior to starting therapy with AMG 211;
Major surgery within 28 days of study day 1.
Females with a positive pregnancy test.;Voor een volledig overzicht van alle inclusie criteria verwijs ik u naar paragraaf 4.2 van het 20130354 protocol.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2014
Enrollment:	31
Type:	Actual

Ethics review

Approved WMO Date:	27-05-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	31-07-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-10-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-12-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-01-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-01-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	

Date:	27-03-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-10-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	03-12-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	04-02-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-07-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	09-08-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-12-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-12-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-04-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	

Date:	23-05-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-08-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-09-2017
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	EUCTR2014-000201-12-NL
ClinicalTrials.gov	NCT02291614
CCMO	NL48544.042.14