An interventional, prospective IVD device study for the testing of DNA extracted from tumor tissue biopsy samples in a first line setting from patients diagnosed with metastatic Colorectal Cancer (mCRC) to determine the KRAS G12C mutation status as part of the inclusion criteria into the Amgen Phase III clinical trial (Protocol No 20210081) to demonstrate clinical performance of the therascreen® KRAS RGQ PCR Kit.

Published: 07-08-2024
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To utilize the therascreen KRAS RGQ PCR Kit, as a screening test in Amgen*s Phase 3 Clinical Study Protocol 20210081, in order to identify patients with mCRC KRAS G12C mutation positive tumors to be enrolled in the drug clinical trial. Results of...

Ethical review	Approved WMO
Status	Pending
Health condition type	Anal and rectal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON56931

Source
ToetsingOnline

Brief title
McLaren Clinical Performance Study of the therascreen® KRAS RGQ PCR Kit

Condition

- Anal and rectal conditions NEC

Synonym
metastatic Colorectal Cancer

Research involving
Human

Sponsors and support

Primary sponsor: QIAGEN Manchester Ltd
Source(s) of monetary or material Support: QIAGEN

Intervention

Keyword: G12C, KRAS, mCRC, therascreen

Outcome measures

Primary outcome

Objective:

To utilize the therascreen KRAS RGQ PCR Kit, as a screening test in Amgen*s Phase 3 Clinical Study Protocol 20210081, in order to identify patients with mCRC KRAS G12C mutation positive tumors to be enrolled in the drug clinical trial. Results of the Phase 3 Amgen Study 20210081 will serve as the basis for establishing the clinical performance of the therascreen KRAS RGQ PCR Kit as a companion diagnostic (CDx) for the identification of patients with metastatic colorectal cancer, who may benefit from treatment with sotorasib.

Endpoint:

To demonstrate that the therascreen KRAS RGQ PCR Kit is safe and effective to identify patients for sotorasib treatment, as supported by the efficacy and

safety endpoints from the sotorasib clinical trial.

Secondary outcome

N/A

Study description

Background summary

N/A - See Objectives and Study Design.

Study objective

To utilize the therascreen KRAS RGQ PCR Kit, as a screening test in Amgen*s Phase 3 Clinical Study Protocol 20210081, in order to identify patients with mCRC KRAS G12C mutation positive tumors to be enrolled in the drug clinical trial. Results of the Phase 3 Amgen Study 20210081 will serve as the basis for establishing the clinical performance of the therascreen KRAS RGQ PCR Kit as a companion diagnostic (CDx) for the identification of patients with metastatic colorectal cancer, who may benefit from treatment with sotorasib.

Study design

The proposed medical device clinical performance study and the medicinal clinical trial will be conducted simultaneously as a combined trial according to MDCG 2022-10. The clinical trial 20210081 is a Randomized, Open-label, Active-controlled Study of Sotorasib, Panitumumab and FOLFIRI Versus FOLFIRI With or Without Bevacizumab-awwb for Treatment-naïve Subjects with Metastatic Colorectal Cancer with KRAS p.G12C Mutation (CodeBreaK 301). It is estimated that approximately 450 patients from 31 countries will be enroled based on the presence of tumor KRAS G12C mutation, detected using the therascreen KRAS RGQ PCR Kit, along with other clinical trial inclusion criteria, into the Phase III clinical trial (Protocol 20210081, Section 5.1 & 5.2). Results from the Phase 3 Amgen Study 20210081 will be used to evaluate the clinical performance of the therascreen KRAS RGQ PCR Kit as a CDx device for identification of patients with mCRC who may benefit from treatment with sotorasib in treatment-naïve patients with metastatic colorectal cancer.

Intervention

Not Applicable, Intervention is the Clinical Trial. Please refer to the Clinical Trial Protocol for details.

Study burden and risks

N/A Please see Clinical Trial Protocol

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

Patients with pathologically documented metastatic CRC. Clinical trial 20210081 inclusion and exclusion criteria can be found in the clinical trial protocol 20210081, Section 5.1 & 5.2.
Subjects who consent to participate in the eligibility screen for Protocol 20210081 will have their tumor tissue tested for the presence of KRAS G12C mutation under the proposed performance study.

Patients identified for inclusion in the Amgen Clinical Study (Protocol No. 20210081), may provide an archival tumor sample collected within 5 years if this is available. A fresh tumor biopsy may be taken at baseline if appropriate archival tissue is not available. Tissue must be fixed in 10% neutral buffered formalin (NBF) and embedded in paraffin.
A Formalin-Fixed Paraffin-Embedded (FFPE) tissue block (preferred), or a minimum of 4 unstained slides (5µm sections), and a copy of the de-identified pathology report is requested for screening. FFPE sections must be mounted on a positively charged glass slide and tested within 111 weeks of sectioning
Acceptable biopsies for tumor tissue include core needle biopsy (CNB) or surgical resection (RES). Fine needle aspiration (FNA), brushings, cell pellets from pleural effusion, bone biopsy and lavage samples are not acceptable.Additional details on the sample requirements are described in section 7 and in the therascreen KRAS RGQ PCR Kit instructions for use (DHF-20-1839-2-DOU-002).

Exclusion criteria

Patients with pathologically documented metastatic CRC. Clinical trial 20210081 inclusion and exclusion criteria can be found in the clinical trial protocol 20210081, Section 5.1 & 5.2.
Subjects who consent to participate in the eligibility screen for Protocol 20210081 will have their tumor tissue tested for the presence of KRAS G12C mutation under the proposed performance study.
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Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-06-2024
Enrollment:	16
Type:	Anticipated

Medical products/devices used

Generic name:	therascreen® KRAS RGQ PCR Kit
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	07-08-2024
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
CCMO	NL85867.000.24