An interventional, prospective IVD device study for the testing of DNA extracted from tumor tissue biopsy samples from adult participants with metastatic Non-Small Cell Lung Cancer (NSCLC) for potential inclusion in the MSD Phase 3 clinical trial (Protocol No MK-1084-004) to demonstrate clinical performance of the therascreen® KRAS RGQ PCR Kit.

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To utilize the therascreen KRAS RGQ PCR Kit (KRAS Kit) as a screening test to identify KRAS G12C mutations in newly diagnosed metastatic NSCLC participants and thereby determine eligibility for enrolment into the Phase 3 clinical study (MK-1084-004...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON57094

Source
ToetsingOnline

Brief title
An interventional prospective IVD device study for the testing of DNA extracted from tumor tissue b

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
Lung cancer

Research involving
Human

Sponsors and support

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

Intervention

- In-vitro diagnostic

Keyword: IVD, KRAS, NSCLC, PCR

Explanation

N.a.

Outcome measures

Primary outcome

Performance study endpoint is to demonstrate that the therascreen KRAS RGQ PCR
Kit is safe and effective to identify participants for MK-1084 treatment, as
supported by the efficacy endpoints from the MK-1084-004 clinical trial.

Secondary outcome

NA

Study description

Background summary

This is an interventional prospective clinical performance study to evaluate the performance of the therascreen KRAS RGQ PCR Kit as a CDx in the MSD Phase 3 clinical trial assessing the safety and effectiveness of a new drug, MK-1084,

in participants with metastatic NSCLC.

Study objective

To utilize the therascreen KRAS RGQ PCR Kit (KRAS Kit) as a screening test to identify KRAS G12C mutations in newly diagnosed metastatic NSCLC participants and thereby determine eligibility for enrolment into the Phase 3 clinical study (MK-1084-004), evaluating the efficacy and safety of MK-1084 in combination with pembrolizumab compared with placebo plus pembrolizumab, to demonstrate the clinical performance of the therascreen KRAS RGQ PCR Kit.

Study design

This is an interventional prospective clinical performance study to evaluate the performance of the therascreen KRAS RGQ PCR Kit as a CDx in the MSD Phase 3 clinical trial assessing the safety and effectiveness of a new drug, MK-1084, in participants with metastatic NSCLC.

All participants will be asked to sign and date an Institutional Review Board/Independent Ethics Committee (IRB/IEC)-approved informed consent form before their formalin-fixed tumor biopsy tissue samples are collected and sent to the Test Sites.

The KRAS test at the device test sites will be used to detect the KRAS G12C mutation in DNA extracted from FFPE tissue samples from participants with metastatic NSCLC, that are treatment-naïve in the metastatic setting, in order to determine KRAS G12C mutation eligibility for enrollment in the MSD Phase 3 clinical study MK-1084-004.

Clinical data will be analyzed as part of the study to determine the device*s clinical utility in KRAS G12C mutated participants receiving MK-1084 in order to support future regulatory filings for the KRAS kit as a CDx for MK-1084.

Intervention

To utilize the therascreen KRAS RGQ PCR Kit (KRAS Kit) as a screening test to identify KRAS G12C mutations in newly diagnosed metastatic NSCLC participants and thereby determine eligibility for enrolment into the Phase 3 clinical study (MK-1084-004).

Study burden and risks

Potential Risks:

A Risk Management Plan was written in line with ISO 14971, and a risk assessment was conducted. The majority of risk has been mitigated through

product design and manufacturing, including investigational device labelling. Given the nature of this device study and the mitigation of identified risks, the residual risk to participants whose sample specimen is tested is acceptable.

The identified potential harm to subjects as a result of KRAS G12C testing are as follows:
• Harm resulting from sample collection
• Harm due to a false negative KRAS G12C result
• Harm due to a false positive KRAS G12C result

Potential benefits:

The therascreen KRAS RGQ PCR Kit is intended for use in clinical trials to aid in the identification of NSCLC participants who harbour KRAS G12C mutation and may be eligible for treatment with MK-1084.

Contacts

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Trial sites

Trial sites in the Netherlands

Isala
Target size: 5

Ziekenhuis St. Jansdal
Target size: 5

Universitair Medisch Centrum Utrecht
Target size: 4

Listed location countries

Canada, France, Georgia, Mexico, United Kingdom, United States, Ukraine, Argentina, Austria, Brazil, Bulgaria, China, Netherlands, Romania, Spain, Chile, Germany, Philippines, Greece, India, Italy, New Zealand, Poland, South Korea

Eligibility criteria

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

Inclusion criteria

Participants who consented to participate in MK-1084-004 will provide an archived tumor tissue (FFPE) sample. If archived tumor tissue is not available, then a fresh tumor tissue sample must be obtained.

Clinical trial samples will only be tested if participants have signed the ICF permitting the use of their samples in the clinical study. Participants must provide a valid tissue sample.

Exclusion criteria

If the biopsy sample doesn*t show a tumor on the Hematoxylin and Eosin (H&E) slide or doesn*t meet device sample requirements, the sample will be considered not evaluable. Participants whose tumor tissue biopsy samples are not evaluable will be excluded from the study. Additionally, participants with samples identified for the study which have insufficient testing material (not sufficient DNA quantity) will also be excluded.

Study design

Design

Study phase: N/A

Study type:	Interventional research previously applied in human subjects
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-02-2025
Enrollment:	14
Type:	Actual

WORLD

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2024
Enrollment:	600
Type:	Actual

Medical products/devices used

Product type:	Medical device
Generic name:	Therascreen® KRAS RGQ PCR Kit
Registration:	Yes - CE outside intended use

IPD sharing statement

Plan to share IPD: No

Plan description
N.a.

Ethics review

Approved WMO

Date:	07-11-2024
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

	(Assen)
Notification accepted Date:	13-05-2025
Application type:	Amendment
Review commission:	METC Stg BEBO

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	NL87190.000.24
Research portal	NL-005469