ValUe of screening MRI brain in patients with newly diagnosed stage IV non-oncogene addicted non-small cell Lung CANcer - The VULCAN trial

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To assess the impact on treatment decision of a screening MRI brain in asymptomatic patients with newly diagnosed stage IV non-oncogene addicted NSCLC, fit for systemic treatment.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Metastases
Study type	Observational invasive

Summary

ID

NL-OMON57100

Source
ToetsingOnline

Brief title
VULCAN

Condition

- Metastases

Synonym
Lung cancer, non-small-cell lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Brain metastasis, Non-small-cell lung cancer, Screening

Outcome measures

Primary outcome

Clinical value of the MRI evaluated by the treating thoracic oncologist to assess the impact on treatment decision of a screening MRI brain in asymptomatic patients with newly diagnosed stage IV non-oncogene addicted NSCLC, fit for systemic treatment.

Secondary outcome

We aim to assess incidence of brain disease, the clinical course of brain metastasis, related symptoms and treatment received in patients with positive and negative screenings MRI throughout the course of disease. We will also perform a cost-benefit analysis of the baseline MRI brain scan in this study population.

Study description

Background summary

Brain metastases frequently arise in patients with lung cancer. They are associated with poor quality of life (QoL) and decreased survival. Patients with brain metastasis are usually excluded from clinical trials, despite the need for improved and more personalized treatment. Knowledge of the presence of asymptomatic brain metastases in the standard of care setting would be of great value to initiate adequate and timely treatment before symptoms arise thereby potentially prolonging the period with a good QoL and survival.

Study objective

To assess the impact on treatment decision of a screening MRI brain in asymptomatic patients with newly diagnosed stage IV non-oncogene addicted NSCLC, fit for systemic treatment.

Study design

Prospective, single center cohort study.

Before start of standard of care treatment, an MRI of the brain will be conducted to screen for brain disease. In case of brain metastases, treatment will be discussed in the multidisciplinary tumor board as part of standard of care. The treating thoracic oncologist will be asked to complete questionnaires regarding therapy and the value of the scan at three time points, before (<3 weeks), right after (<= 3 weeks) and a while after (3-6 months) the MRI.

Study burden and risks

Patients participating in this study will have an extra MRI of the brain (approximately 40 min). This potentially can cause psychological distress. If feasible, the scan will be planned together with standard of care evaluations to minimize burden for the patient. In case of a separate appointment for the trial, travel and parking costs will be reimbursed.

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

•Capable of giving signed informed consent.
•Age >=18 years at the time of screening.
•Histologically or cytologically confirmed stage IV metastatic NSCLC, not amenable to curative treatment.
•Fit for systemic treatment (PS 0-2) according to standard of care.
•No symptoms of brain disease assessed according to standard clinical care by the thoracic oncologist.

Exclusion criteria

•Prior/concomitant therapy for stage IV disease.
•Oncogenic diver mutation (e.g. EGFR, ALK, ROS1, RET, MET, and BRAF) with approved targeted treatment.
•Contraindications for MRI scan with contrast as per standard of care protocol of the institution.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-08-2024
Enrollment:	100
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	24-04-2024
Application type:	First submission
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
CCMO	NL84338.042.23