Screening for brain metastasis in patients with stage III Non-Small Cell Lung Cancer: Has Magnetic Resonance Imaging an additive value compared to contrast enhanced Computed Tomography of the brain Incorporated in the staging whole body 18FDG-PET-CT scanning?

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25283

Source
Nationaal Trial Register

Brief title
ARCTIC

Health condition

Non Small Cell Lung Cancer, brain metastases, MRI, 18FDG-PET-CT with contrast enhanced CT brain

niet kleincellig longkanker, hersenmetastasen, MRI, 18FDG-PET-CT met diagnostische CT van het brein

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Number of patients with additional brain metastasis found on MRI after negative CE-CT.

Secondary outcome

1. Asymptomatic brain metastasis found on 18FDG-PET-CE-CT in otherwise stage III NSCLC patients;

2. Cost analysis;

3. Number of patients with symptomatic brain metastasis within a year after an initially negative MRI and time to symptomatic brain metastasis.

Study description

Background summary

In current NSCLC guidelines imaging of the brain is advised in all stage III patients eligible for therapy with curative intent. MRI is preferred to contrast enhanced CT of the brain (CE-CT), but this advise is based on older studies. These studies did not include only (stage III) NSCLC nor 18FDG-PET. In a recently performed retrospective study using up-to-date MRI and CT techniques, no additional brain metastasis were found on MRI in patients with stage III NSCLC after 18FDG-PET-CT with CE-CT of the brain. Moreover, in most hospitals MRI availability is scarce and MRI is difficult to obtain within a reasonable time scale. Also, MRI adds extra costs to the diagnostic evaluation. Finally, there are also some contra-indications for MRI, for example intracorporal metallic objects, pacemakers and claustrophobia.

Although it is known that MRI of the brain is more sensitive than a CE-CT, it is unclear whether this is still the case in the setting of excluding brain metastasis in neurological asymptomatic patients with stage III NSCLC.

The question whether post contrast MRI offers a benefit to CE-CT in the initial staging of patients with NSCLC has become more urgent in view of the increasing wide-spread use of 18FDG-PET-CT scanners. If CE-CT performed in the same setting as 18FDG-PET-CT could lead to the same yield of brain metastasis detection as 18FDG-PET-CT with LD-CT and separately a post contrast MRI, a substantial gain in time and resources can be expected without increasing the radiation dose and quantity of contrast agent administered to the patient.

We hypothesise that there is no clinically relevant additive value of post contrast MRI to CE-CT of the brain when both are performed in standard work-up, including 18FDG-PET-CE-CT, in detecting asymptomatic brain metastasis.

Study objective

We hypothesise that there is no clinically relevant additive value of post contrast MRI to contrast enhanced computed tomography (CE-CT) of the brain when both are performed in standard work-up, including 18FDG-PET-CE-CT, in detecting asymptomatic brain metastasis.

Clinically relevant is defined by our study group as: additional brain metastasis found on MRI in more than two out of one hundred patients who have a negative 18FDG-PET-CE-CT. We base this number on the fact that already up to 15% of stage III NSCLC patients develop symptomatic brain metastasis within a year after an initial negative MRI.

Study design

Follow up will be one year.

Intervention

None, observational.

Contacts

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Eligibility criteria

Inclusion criteria

1. Pathology proven NSCLC;

2. UICC stage III;

3. Eligible for therapy with curative intent;

4. Staging based on 18FDG-PET-CE-CT;

5. No contra-indication for MRI or CE-CT;

6. MRI within 3 weeks after 18FDG-PET-CE-CT.

Exclusion criteria

1. Other malignancy that is not controlled or that was diagnosed less than 2 years before enrolment in this study, except skin cancer or cervical cancer in situ;

2. Contra-indication for MRI or CE-CT;

3. Mixed histologies such as combined small cell and non-small cell lung cancer;

4. Recurrent disease only if not eligible for therapy with curative intent.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2012
Enrollment:	118
Type:	Actual

Ethics review

Positive opinion

Date:	24-09-2012
Application type:	First submission

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
NTR-new	NL3335
NTR-old	NTR3628
Other	METC acM/UM : 12-4-126
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
Schoenmaekers, J., Hendriks, L. E., Hofman, P. et al, JTO 2016; 12:S1:MA06.05

Schoenmaekers et al, 1365PD - Screening for brain metastases (BM) in patients (pts) with stage III non-small cell lung cancer (NSCLC), magnetic resonance imaging (MRI) or dedicated contrast-enhanced computed tomography (dCE-CT)? A prospective observational study