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# Tumor volume measurements vs diameter-based measurements (mRECIST) for response evaluation in pleural mesothelioma

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 31/12/2023 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 15/01/2024 | Ongoing | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 15/01/2024 | Cancer | [ ] Record updated in last year |

## Plain English summary of protocol

Background and study aims
Pleural mesothelioma (PM) is an aggressive type of cancer that arises from the pleural mesothelium, a thin layer covering the lungs and chest wall. The aim of this study is to investigate whether using the tumour volume makes the response evaluation more reliable compared to the current mRECIST criteria (diameter-based measurements).

Who can participate?
Patients aged 18 years and over with pleural mesothelioma

What does the study involve?
All patients will be treated by their own treating physician. However, during this study, an additional response evaluation based on tumor volume will be conducted. Treatment decisions will not be based on this evaluation.

What are the possible benefits and risks of participating?
There are no side effects nor possible benefits for the patients when participating. The researchers will gain more knowledge about the response evaluation system.

Where is the study run from?
Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital (Netherlands)

When is the study starting and how long is it expected to run for?
June 2023 to December 2025

Who is funding the study?
Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital (Netherlands)

Who is the main contact?
Sjaak Burgers, s.burgers@nki.nl

# Contact information

### Type(s)
Public, Scientific


### Contact name
Ms Illaa Smesseim

### Contact details
Plesmanlaan 121
Amsterdam
Netherlands
1066 CX
+31 (0)205129111
i.smesseim@nki.nl


### Type(s)
Principal Investigator


### Contact name
Dr Sjaak Burgers

### Contact details
Thoracic Oncology / Plesmanlaan 121
Amsterdam
Netherlands
1066 CX
+31 (0)644137161
s.burgers@nki.nl


# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
IRBd23-265

# Study information

### Scientific Title
COMET trial: Comparison of pleural mesothelioma evaluation using volume measurements with an artificial intelligence program to the mRECIST v1.1 criteria, a prospective trial

## Acronym
COMET

## Study objectives
ARTIMES yields an equal or higher interobserver agreement between different radiologists compared to mRECIST v1.1.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
Approved 04/12/2023, Institutional Review Board (IRB) The Netherlands Cancer Institute (Plesmanlaan 121, Amsterdam, 1066 CX, Netherlands; +31 (0)20 51291; IRB@nki.nl), ref: IRBd23-265

## Study design
Prospective blinded comparative non-inferiority single-centre feasibility study

## Primary study design
Observational

## Secondary study design
Feasibility study

## Study setting(s)
Hospital

## Study type(s)
Diagnostic

## Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
Pleural mesothelioma

## Interventions
This is a prospective blinded comparative non-inferiority single-center feasibility study. Three radiologists will review every CT scan of adult patients with pleural mesothelioma referred to the tertiary center according to the mRECIST v1.1 and ARTIMES. Confirmation bias could occur if a radiologist assigns progressive disease (PD) following mRECIST v1.1 and is afterwards segmenting extra volume to ensure a PD for ARTIMES as well. To reduce this bias, the same CT scan needs to be reviewed for mRECIST and ARTIMES on different days with a washout of at least 4 weeks. The sequence in which both methods are used will be random. Reviewers will be blinded for their own results and for the results of the other reviewers.

## Intervention Type
Other

## Primary outcome measure

The interobserver agreement among experts employing the ARTIMES criteria and the gold standard (mRECIST v1.1 criteria), measured at the end of the study using kappa

### Secondary outcome measures
1. Time needed to measure response evaluation in minutes between the ARTIMES vs mRECIST v1.1 criteria, measured in minutes for every scan at every evaluation point
2. Time until partial response (PR) and progressive disease (PD) in days between the ARTIMES vs mRECIST v1.1 criteria, measured in days at every evaluation point
3. The response evaluation of the treating physician with the ARTIMES criteria and the mRECIST v1.1. criteria per evaluation point, compared at every evaluation point
4. The performance of the AI in segmenting pleural mesothelioma tumour volume vs the final segmentation of the reviewers, compared at every evaluation point

### Overall study start date
01/06/2023

### Completion date
31/12/2025

## Eligibility

### Key inclusion criteria
1. Histology or cytology-proven non-resectable pleural mesothelioma
2. Age ≥18 years
3. Availability of a baseline CT thorax with contrast before the start of new systemic treatment with a slice increment of ≤3 mm on the CT scan
4. Availability of at least one follow-up scan (the lungs must be fully contained in the image)

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
52

### Key exclusion criteria
1. CT scans with lungs not fully imaged
2. No histology-proven pleural mesothelioma

### Date of first enrolment
01/12/2023

**Date of final enrolment**
01/01/2025

# Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**Antoni van Leeuwenhoek hospital / NKI**
Plesmanlaan 121
Amsterdam
Netherlands
1066 CX

# Sponsor information

**Organisation**
Antoni van Leeuwenhoek Hospital

**Sponsor details**
Thoracic Oncology / Plesmanlaan 121
Amsterdam
Netherlands
1066 CX
+31 (0)644137161
s.burgers@nki.nl

**Sponsor type**
Hospital/treatment centre

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital

# Results and Publications

## Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

## Intention to publish date
01/04/2023

## Individual participant data (IPD) sharing plan
The data will be stored for at least 20 years and as long as proven useful for scientific research.

## IPD sharing plan summary
Available on request