

# Multicenter segmentectomy in VR

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Additional value of 3D-VR over 2D-CT will show that lung surgery will be in some cases more lung sparing or will result in better preoperative planning by having more information about important parameters (resection margin, anatomic variation) that...

|                             |                                                     |
|-----------------------------|-----------------------------------------------------|
| <b>Ethische beoordeling</b> | Positief advies                                     |
| <b>Status</b>               | Werving nog niet gestart                            |
| <b>Type aandoening</b>      | -                                                   |
| <b>Onderzoekstype</b>       | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON27754

### Bron

NTR

### Verkorte titel

MUSEVIR

### Aandoening

Lung carcinoma (NSCLC), benign pathologie (bronchiectasis, hamartoma) or metastatic pulmonary lesion

### Ondersteuning

**Primaire sponsor:** None

**Overige ondersteuning:** Koers23, Erasmus MC

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

Additional value of advanced imaging (based on 3D-VR and AI technology) over 2D-CT

# Toelichting onderzoek

## Achtergrond van het onderzoek

VR-guided segmentectomies have shown a 50% change of surgical plan compared to 2D-CT planned segmentectomies. In this multicenter study, 100 patients will be included, coming from 6 to 7 different centers in The Netherlands, to determine the additional value of advanced imaging (based on 3D-VR and artificial intelligence) compared to conventional CT planning on the surgical strategy for lung segmentectomy. During 1 year, patients with early stage lung cancer, metastatic pulmonary lesions or benign pathology, suitable for segment resection based on multidisciplinary discussion, will be included. First, all centers will set up an operative plan based on 2D-CT (approach, which segments need to be resected etc). Meanwhile, researchers make the conventional CT VR-ready and redistribute the 3D-VR images over all participating centers. Then, all centers will make a new operative plan. Operating center is blinded to the results of other centers, but can adjust its surgical plan based on the 3D-VR images. Afterwards, perioperative outcomes and pathological outcomes will be collected.

## Doel van het onderzoek

Additional value of 3D-VR over 2D-CT will show that lung surgery will be in some cases more lung sparing or will result in better preoperative planning by having more information about important parameters (resection margin, anatomic variation) that will make lung resection surgery more safe en tumor specific will result in an oncological better radical resection.

## Onderzoeksopzet

The primary outcome: 3D-VR planning vs 2D-CT planning and its operative plan will be determined 1 to 2 weeks after patient inclusion and before surgery. The perioperative parameters will be collected 1 month after surgery (to include all complications that could have occurred in the 30 days after surgery).

# Contactpersonen

## Publiek

Erasmus MC  
Wouter Bakhuis

0618661770

## Wetenschappelijk

Erasmus MC  
Wouter Bakhuis

0618661770

## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Indication for lung segment resection. Patient older than 18 years, operation planned in one of participating centers. Diagnostic CT thorax with max slice width of 1,5mm available. (High suspicion of ) lung carcinoma NSCLC stage 1A1/1A2 (cT1a/bN0M0) not centrally located and suitable for segment resection, or benign pathology (ie hamartoma) suitable for segment resection, or metastatic pulmonary lesion (extra thoracic origin or reoccurring lung carcinoma) suitable for segment resection

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

No informed consent for using VR as preoperative tool, patient wish for lobectomy instead of segmentectomy, not suitable for segmentectomy based on preoperative screening

## Onderzoeksopzet

### Opzet

Type: Observationeel onderzoek, zonder invasieve metingen  
Onderzoeksmodel: Anders  
Toewijzing: N.v.t. / één studie arm  
**Controle:** N.v.t. / onbekend

### Deelname

Nederland  
Status: Werving nog niet gestart

(Verwachte) startdatum: 01-01-2022  
Aantal proefpersonen: 100  
Type: Verwachte startdatum

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

## Ethische beoordeling

Positief advies  
Datum: 04-09-2021  
Soort: Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register       | ID                                                                                   |
|----------------|--------------------------------------------------------------------------------------|
| NTR-new        | NL9767                                                                               |
| Ander register | METC Erasmus MC (+ METC of all participating centers will follow) :<br>MEC-2020-0702 |

## Resultaten