Multicenter segmentectomy in VR

No registrations found.

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

Summary

ID

NL-OMON27754

Source NTR

Brief title MUSEVIR

Health condition

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

Sponsors and support

Primary sponsor: None Source(s) of monetary or material Support: Koers23, Erasmus MC

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Percentage change of plan due to 3D-VR planning, percentage more lung sparing, preoperative planning time of 3D-VR and 2D-CT, consensus between different participating

1 - Multicenter segmentectomy in VR 10-05-2025

centers. Similarities between parameters in 3D-VR and real-life, Ease-of-use of 3D-VR software, perioperative outcomes of VR-guided segmentectomies.

Study description

Background summary

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 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.

Study objective

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.

Study design

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).

Contacts

Public Erasmus MC Wouter Bakhuis 0618661770 **Scientific** Erasmus MC Wouter Bakhuis

0618661770

Eligibility criteria

Inclusion criteria

Indication for lung segment resection. Patient older than 18 years, operation planned in one of participating centers. Diagnostic CT thorax with max slide 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 reoccuring lung carcinoma) suitable for segment resection.

Exclusion criteria

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

Study design

Design

Study type:Observational non invasiveIntervention model:OtherAllocation:Non controlled trialControl: N/A , unknownValue

Recruitment

NL Recruitment status: Pending Start date (anticipated): 01-01-2022

Enrollment:		
Туре:		

Anticipated

100

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinionDate:04-09-2021Application 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 NL9767

Other METC Erasmus MC (+ METC of all participating centers will follow) : MEC-2020-0702

Study results

4 - Multicenter segmentectomy in VR 10-05-2025