# Laparoscopic laser speckle contrast imaging for the demarcation of lung segments

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In this trial we will study the utility of PerfusiX-Imaging for the identification of intersegmental planes during thoracoscopic segmentectomy.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory tract neoplasms
Study type	Observational non invasive

### Summary

#### ID

NL-OMON51469

**Source** ToetsingOnline

**Brief title** PORTION-I

#### Condition

- Respiratory tract neoplasms
- Respiratory tract therapeutic procedures

#### Synonym

Lungcancer

#### **Research involving** Human

#### **Sponsors and support**

Primary sponsor: LIMIS Development BV Source(s) of monetary or material Support: LIMIS Development BV

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#### Intervention

Keyword: imaging, Laser Speckle, lung cancer, lung segments

#### **Outcome measures**

#### **Primary outcome**

Due to the explorative character of this study, there is no formal hierarchy in the respective endpoints of this study. In this, all endpoints will add to the overall assessment of the feasibility of the PerfusiX-imaging derived visual feedback Als laatste

for detecting interlobar and intersegmental planes in lung tissue. We will compare the difference in location of both the interlobar and intersegmental planes as derived from visual feedback from the PerfusiX-imaging system, with images derived from ICG imaging and the surgical eye. During the procedure, the time needed to generate and acquire the visual feedback from the PerfusiX-imaging system will be determined. We will also determine the interpretability of the visual feedback from the PerfusiX-imaging system by users (surgeons). In addition, we will determine Laser Speckle Perfusion Unit (LSPU) cut-off values of PerfusiX-imaging in lung tissue with the highest sensitivity and specificity for the indication of level of tissue perfusion.

#### Secondary outcome

Not applicable

## **Study description**

#### **Background summary**

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Lung cancer remains to be the leading cause of cancer-related deaths worldwide1. The current standard-of-care for small lung cancer is a total lobectomy. Albeit effective with respect to the radical excision of the tumour, the substantial loss in lung tissue may be clinically relevant, especially in combination with frequently co-existing lung diseases. Thoracoscopic segmentectomy is a combination of adequate oncological resection with lung-tissue-sparing properties and is being increasingly used because of its several advantages compared with lobar resections. By defining the segment that has to be excised pre-operatively, the key to successful pulmonary segmentectomy is to subsequently intraoperatively recognize the intersegmental planes correctly. The conventional and most common method uses a ventilation method (inflation/deflation technique). With the increasing availability of laparoscopic imaging systems, indocyanine green (ICG) fluorescence imaging is a more advanced method to determine intersegmental planes. The major limitation is the use of an exogenous contrast agent. After injection, the ICG only has very limited \*imaging time window\* (minutes) in which the images can be used to determine the intersegmental planes. Furthermore, the use of dye limits repeatability of measurements due to rest ICG, the extra operating room time required for the injection, wash-in and wash-out of the dye as well as change of camera settings. These limitations leave room for new technologies and improvements. We hypothesized that a laparoscopic laser speckle imaging device could overcome the limitations of ICG-fluorescence imaging and could thus be a very useful addition in intersegmental plane detection. PerfusiX-Imaging (LIMIS Development BV, Leeuwarden, The Netherlands) is such a laparoscopic laser speckle contrast imager that has been developed in the Medical Centre Leeuwarden since 2014. LSCI has never been used to identify intersegmental planes, however, based on the similarities between LSCI and ICG-fluorescence, this novel imaging approach is thought to be effective and potentially could be used as a standard-of-care.

#### **Study objective**

In this trial we will study the utility of PerfusiX-Imaging for the identification of intersegmental planes during thoracoscopic segmentectomy.

#### Study design

The current study is a prospective, observational single-centre study in the Medical Center Leeuwarden.

#### Study burden and risks

The total surgery is expected to take 5 minutes longer. There are no known risks. Patients did not directly benefit from this study. The surgery proceeds as normal, with the addition of the additional perfusion measurements. During

the operation, no decisions are made on the laser speckle images.

### 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**

Scheduled to undergo upper left or right lobectomy

### **Exclusion criteria**

Medical or psychiatric conditions that compromise the patient\*s ability to give informed consent

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# Study design

### Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	02-01-2023
Enrollment:	10
Туре:	Actual

### Medical products/devices used

Generic name:	PerfusiX-Imaging
Registration:	No

# **Ethics review**

Approved WMO	17 10 2022
Date:	17-10-2022
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

# **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** ClinicalTrials.gov CCMO

ID NCT05545085 NL82338.099.22