# The Enhanced Recovery After Thoracic Surgery (ERATS) Trial

Published: 15-05-2025
Last updated: 22-05-2025

Determine the optimal set of implementation strategies to introduce ERATS in the Netherlands; evaluate whether high protocol adherence indeed leads to the expected reduction in length of hospital stay, complications, and readmissions, alongside...

| | |
|---|---|
| **Ethical review** | Not available |
| **Status** | Pending |
| **Health condition type** | Respiratory tract neoplasms |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON57541

**Source**
Onderzoeksportaal

**Brief title**
ERATS Trial, Implementation of an Enhanced Recovery After Thoracic Surgery protocol in the Netherlands

### Condition

- Respiratory tract neoplasms

**Synonym**
Lung Cancer

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Albert Schweitzer Ziekenhuis
**Source(s) of monetary or material Support:** Derde geldstroom (anders, zoals collectebussenfondsen, Europese Unie, vakministeries of bedrijven)

## Intervention

- Other intervention

### Explanation

N.a.

## Outcome measures

### Primary outcome

The primary objective of this study is to achieve a 15% improvement in ERATS protocol adherence, increasing from an estimated 65% to over 80%, in relation to the completion of the ERATS implementation trajectory.

### Secondary outcome

Secondary objectives include reducing the length of hospital stay by one day (from six to five days), shortening the time to recovery, decreasing complication and readmission rates, lowering mortality rates, and enhancing patient-reported outcomes measured by EORTC QLQ-C30, EORTC QLQ-LC13, and PROMIS-APS.

# Study description

### Background summary

In the Netherlands, more than 2,200 anatomical lung resections are performed annually. However, perioperative care surrounding these surgeries varies significantly, resulting in differences in length of hospital stay (median 4–8 days) and complication rates. An analysis of the Netherlands Comprehensive Cancer Organisation (IKNL) database and the Dutch Lung Cancer Audit-surgery (DLCA-s) database suggests that this variation cannot be attributed to patient or tumor characteristics but is instead associated with differences in perioperative care, including drain management, pain management, patient education, and mobilization. This impression was confirmed by a survey conducted among all Dutch thoracic surgical centers regarding perioperative care for patients undergoing lung resection.

While the goals of high-quality perioperative care (rapid recovery after surgery, no complications, no readmissions, and high patient satisfaction) are widely shared, an integrated perioperative care protocol is currently lacking in the Netherlands. In other surgical fields, Enhanced Recovery After Surgery (ERAS®) programs have led to reductions in hospital length of stay, complications, readmissions, and costs, along with an increase in the perceived quality of care among patients and healthcare providers. The recently published

ERAS® Society / European Society of Thoracic Surgeons (ESTS) guideline for lung resection patients provides a framework to achieve these goals by optimizing and standardizing perioperative care for patients undergoing anatomical lung resection.

To achieve this in the Netherlands, an Enhanced Recovery After Thoracic Surgery (ERATS) care protocol has been developed based on the recommendations from the ERAS®/ESTS guideline. This protocol now needs to be implemented and evaluated. Despite the demonstrated substantial variation in clinically relevant outcomes related to differences in perioperative care practices, the adoption and implementation of a multidisciplinary care protocol by healthcare providers in routine practice remain a challenge. This project aims to evaluate both the effectiveness of the ERATS protocol in improving clinical and patient-reported outcomes, as well as the effectiveness of ERATS implementation, specifically focusing on its integration into routine practice outside of a research setting.

## Study objective

Determine the optimal set of implementation strategies to introduce ERATS in the Netherlands; evaluate whether high protocol adherence indeed leads to the expected reduction in length of hospital stay, complications, and readmissions, alongside improved quality of life and social participation.

## Study design

This will be achieved through a prospective observational study conducted in 10 centers, comparing the extent to which ERATS is adhered to following the implementation of this new standard of care. By relating this adherence to the degree of adherence to the implementation plan, the most effective implementation strategy can be determined. Additionally, clinical and patient-reported outcomes will be compared before and after the implementation of ERATS, using a retrospective cohort from 2018 (just before the publication of the first international guideline in this field) as a reference. These data will primarily consist of information already recorded for national audit purposes and routine documentation in the electronic patient record (EPR). If the standard patient-reported outcome questionnaires are not yet part of routine care in a participating hospital, they will be distributed through the study.

## Intervention

Given the observational nature of the study, there is no intervention involved. All patients in a participating center will be treated according to the new ERATS standard care protocol after its implementation, regardless of their participation in the study.

## Study burden and risks

No additional burden is expected for participants, except for completing PROMs questionnaires at three time points as part of the study. In some hospitals, these questionnaires are already part of routine care and will not be considered an extra burden for

participants. However, in hospitals where PROMs questionnaires are not yet part of routine care, completing them may be viewed as an additional burden. Each completion of the PROMs questionnaires is expected to take approximately 15 minutes.

# Contacts

**Scientific**
Albert Schweitzer Ziekenhuis
EM von Meyenfeldt
Albert Schweitzerplaats 25
Dordrecht 3318AT
Netherlands
0786541111
**Public**
Albert Schweitzer Ziekenhuis
EM von Meyenfeldt
Albert Schweitzerplaats 25
Dordrecht 3318AT
Netherlands
0786541111

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Patients aged 18 years or older undergoing anatomical lung resection for suspected or confirmed lung cancer were eligible for inclusion. Written informed consent

## Exclusion criteria

Not meeting inclusion criterium

# Study design

## Design

| | |
|---|---|
| Study phase: | N/A |
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | No intervention |
| Primary purpose: | Health services research |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-09-2020 |
| Enrollment: | 700 |
| Duration: | 3 months (per patient) |
| Type: | Anticipated |

## Medical products/devices used

| | |
|---|---|
| Product type: | N.a. |

## IPD sharing statement

**Plan to share IPD:** Undecided

**Plan description**
N.a.

# Ethics review

Not available

| | |
|---|---|
| Date: | 20-05-2025 |
| Application type: | First submission |
| Review commission: | Validatie nWMO registratie door CCMO |

# 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 |
|---|---|
| Research portal | NL-010060 |