

# Physical prehabilitation in patients with head and neck cancer scheduled for a laryngectomy; a feasibility study

Published: 19-02-2025

Last updated: 07-03-2025

The aim of this study is both a feasibility study to gain a comprehensive understanding of the feasibility, satisfaction and impact, and trends of the effects of a physical exercise and nutritional intervention in patients who will be treated by a...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Miscellaneous and site unspecified neoplasms benign
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON57310

### Source

ToetsingOnline

### Brief title

PreLa

### Condition

- Miscellaneous and site unspecified neoplasms benign
- Head and neck therapeutic procedures

### Synonym

Laryngeal removal

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Nederlands Fonds tegen Kanker

## Intervention

**Keyword:** Feasibility study, Head and neck cancer, Laryngectomy, Prehabilitation

## Outcome measures

### Primary outcome

Adherence and compliance of the physical exercise intervention and the participants\* experiences of the physical exercise intervention.

### Secondary outcome

- \* Recruitment of patients
- \* Retention rate
- \* Compliance with nutritional prescription
  
- \* Physical fitness (6MWT, SRT)
- \* Physical muscle strength (grip strength, lower and upper muscle strength, 30s-SCT, 8-RM).
- \* Physical activity (SQUASH)
- \* Body composition (FFM by BIA, BMI)
- \* Nutritional status (PG-SGA).
- \* Quality of life (EORTC-QLQ-C30, EORTC-QLQ-H&N35, EQ-5D-5L)
- \* Fatigue (MFI)
- \* Surgical complications and adverse events (Clavien-Dindo classification and adverse events until 3 to 4 weeks after laryngectomy, CTCAE).

## Study description

## **Background summary**

In people with cancer, sarcopenia is often present at the time of diagnosis, typically due to a combination of factors such as disease activity, inactivity and malnutrition. In individuals undergoing surgical treatment for their cancer, those with sarcopenia experience more postoperative complications, longer hospital stays, and shorter overall survival. It is of importance to address the degree of sarcopenia before a laryngectomy.

## **Study objective**

The aim of this study is both a feasibility study to gain a comprehensive understanding of the feasibility, satisfaction and impact, and trends of the effects of a physical exercise and nutritional intervention in patients who will be treated by a total laryngectomy.

## **Study design**

Prospective feasibility study

## **Intervention**

A moderate to high-intensity personalized physical exercise intervention combined with a nutritional intervention will take place in 7 patients 3 to 5 weeks prior to their total laryngectomy.

## **Study burden and risks**

Visits scheduled for assessments will be combined with the laryngectomy treatment-related visits as much as possible. Dietary treatment follow-up visits will be done by telephone. The physical exercise program will be supervised three times per week by an oncology physiotherapist at private physiotherapy practices as close as possible to home and three other days of that week the patient will be active for at least 30 minutes.

The patient will be asked two times to spend, at most, 30 minutes completing questionnaires and two times to spend at most 90 minutes performing physical and nutritional tests and keep an activity and food diary (weekly) and to participate in one semi-structured interview (30 minutes). These tests, diaries and questionnaires have been used in an exercise intervention study during head and neck cancer related radiotherapy.

As in any exercise situation, injuries due to exercise can occur; to minimize the risk, the intensity of the exercise program will be gradually increased during the study and the program will be supervised by a physiotherapist. The estimated extra risk for the patient while participating in this study is low. Possible benefits for participants are a reduction in fatigue, an increase of physical fitness and less total laryngectomy related complications possibly

leading to prosperous recovery and better quality of life.

## Contacts

### Public

Universitair Medisch Centrum Utrecht

Heidelberglaan 100

Utrecht 3584 CX

NL

### Scientific

Universitair Medisch Centrum Utrecht

Heidelberglaan 100

Utrecht 3584 CX

NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Subject must undergo a laryngectomy
- Low skeletal muscle mass (SMM) (see also paragraph 8.1.3), based on CT or MRI scans of the head and neck area at level C3.
- Karnofsky Performance status >60
- Able to walk >=6 m without a mobility aid
- >=18 years
- Sufficient Dutch writing and reading skills

## Exclusion criteria

- Patients exercising more than in the prescribed physical exercise intervention of this study
- For patients participating in the physical exercise and nutritional intervention: <3 weeks to participate in the study intervention

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Treatment

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	14
Type:	Anticipated

### Medical products/devices used

Registration:	No
---------------	----

## Ethics review

Approved WMO	
Date:	19-02-2025
Application type:	First submission
Review commission:	METC NedMec

## 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
CCMO	NL87134.041.24