

# Prognostic value of pretreatment imaging parameters for recurrent laryngeal and hypopharyngeal carcinoma after primary radiotherapy; a retrospective study.

No registrations found.

|                              |                            |
|------------------------------|----------------------------|
| <b>Ethical review</b>        | Positive opinion           |
| <b>Status</b>                | Pending                    |
| <b>Health condition type</b> | -                          |
| <b>Study type</b>            | Observational non invasive |

## Summary

### ID

NL-OMON24461

### Source

NTR

### Brief title

PROVARE

### Health condition

Larynx and hypopharynx carcinoma

## Sponsors and support

**Primary sponsor:** UMC Utrecht

**Source(s) of monetary or material Support:** KWF Kankerbestrijding

## Intervention

## Outcome measures

### Primary outcome

The effect of imaging variables (e.g. apparent diffusion coefficient, tumor volume, and dynamic contrast enhanced MRI variables) on treatment outcome.

### **Secondary outcome**

The effect of clinical variables (e.g. smoking status and tumor stage) on treatment outcome

## **Study description**

### **Background summary**

More and more laryngeal and hypopharyngeal patients receive larynx-preservation treatment instead of total laryngectomy (TLE). However, for some patients, treatments like primary radiotherapy might not be suitable and they risk undertreatment. This study aims to find imaging features on pretreatment imaging that predict outcome of radiotherapy in order to optimise patient selection for this treatment. This can help treatment decision making and increase survival rates.

### **Study objective**

We expect to find that tumor volume, as well as dynamic contrast enhanced MRI variables will be prognostic variables of treatment outcome

### **Study design**

This is a retrospective study, we will gather clinical and treatment related data, as well as imaging from the time of diagnosis until last follow-up.

### **Intervention**

Radiotherapy with or without chemotherapy

## **Contacts**

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## Eligibility criteria

### Inclusion criteria

Patients with larynx or hypopharynx carcinoma primarily treated with radiotherapy with curative intent with or without additional chemotherapy. Treated in UMC Utrecht in the period of January 2008 and March 2020. Follow-up of at least 2 years or until recurrence. Available MRI imaging of the tumor site is made within 4 weeks before the start of the radiotherapy treatment.

### Exclusion criteria

History of carcinoma at the time of diagnosis. Distant metastasis or second primary tumours at time of diagnosis.

## Study design

### Design

|                     |                            |
|---------------------|----------------------------|
| Study type:         | Observational non invasive |
| Intervention model: | Other                      |
| Allocation:         | Non controlled trial       |
| Masking:            | Open (masking not used)    |
| Control:            | N/A , unknown              |

### Recruitment

|                           |             |
|---------------------------|-------------|
| NL                        |             |
| Recruitment status:       | Pending     |
| Start date (anticipated): | 13-01-2021  |
| Enrollment:               | 500         |
| Type:                     | Anticipated |

## IPD sharing statement

**Plan to share IPD:** No

## Ethics review

Positive opinion

Date: 13-01-2021

Application 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  | NL9212                     |
| Other    | METC Utrecht : METC 20-340 |

## Study results