

# Fluorodeoxyglucose-positron emission tomography for avoidance of futile direct laryngoscopies under general anaesthesia with taking of biopsies in patients with suspicion on recurrent laryngeal carcinoma after radiotherapy

<b>Submission date</b> 12/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/09/2008	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr R de Bree

**Contact details**  
Boelelaan 1117  
Department of Otolaryngology /Head and Neck Surgery  
Vrije University Medical Centre  
Amsterdam  
Netherlands  
1081 HV  
+31 (0)20 444 3690  
r.bree@vumc.nl

## Additional identifiers

**Protocol serial number**

## Study information

### Scientific Title

### Acronym

RELAPS: REcurrent LAryngeal carcinoma PET Study

### Study objectives

Not provided at time of registration

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval received from the local medical ethics committee

### Study design

Randomised, active controlled, parallel group trial

### Primary study design

Interventional

### Study type(s)

Prevention

### Health condition(s) or problem(s) studied

Laryngeal carcinoma

### Interventions

Selection for direct laryngoscopy with fluorodeoxyglucose-positron emission tomography (FDG-PET). Two strategy arms are compared:

1. Conventional strategy: direct laryngoscopy under general anaesthesia with taking of biopsies
2. PET based strategy: only direct laryngoscopy under general anaesthesia with taking of biopsies if FDG-PET is positive or equivocal

### Intervention Type

Drug

### Phase

Not Specified

### Drug/device/biological/vaccine name(s)

Fluorodeoxyglucose

### Primary outcome(s)

Number of direct laryngoscopies (on a group level) needed to detect (a single) recurrent laryngeal carcinoma.

**Key secondary outcome(s)**

Key:

1. Costs
2. Operability of a recurrence
3. Surgical margins of the salvage laryngectomy
4. Quality of life

**Completion date**

30/06/2007

**Eligibility****Key inclusion criteria**

1. Patients with clinical suspicion on recurrent laryngeal carcinoma after radiotherapy (without obvious signs of tumour), in whom a direct laryngoscopy under general anaesthesia with taking of biopsies is indicated
2. T2 - T4 laryngeal carcinoma

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Aged less than 18 years
2. Pregnancy
3. Radiotherapy within the last four months

**Date of first enrolment**

01/02/2005

**Date of final enrolment**

30/06/2007

**Locations****Countries of recruitment**

Netherlands

**Study participating centre**

**Boelelaan 1117**  
Amsterdam  
Netherlands  
1081 HV

## **Sponsor information**

### **Organisation**

Vrije University Medical Centre (VUMC) (The Netherlands)

### **ROR**

<https://ror.org/00q6h8f30>

## **Funder(s)**

### **Funder type**

Research organisation

### **Funder Name**

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration