

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Primary study design

Interventional

Study design

Randomised, active controlled, parallel group trial

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
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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