

FDG-PET for avoidance of futile direct laryngoscopies under general anaesthesia with taking of biopsies in patients with suspicion on recurrent laryngeal carcinoma after radiotherapy.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23769

Source

Nationaal Trial Register

Brief title

N/A

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Key:

1. Costs;

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

Study description

Background summary

N/A

Study objective

N/A

Intervention

Selection for direct laryngoscopy with 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.

Contacts

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Eligibility criteria

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.

Exclusion criteria

1. Age < 18 year;
2. Pregnancy;
3. Radiotherapy within the last 4 months.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-02-2005
Enrollment:	150

Type: Anticipated

Ethics review

Positive opinion

Date: 21-01-2005

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	NL62
NTR-old	NTR93
Other	: ZON-MW 945-04-311 2004/036 (projectnummer VUmc)
ISRCTN	ISRCTN89530459

Study results

Summary results

N/A