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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

Registration date
12/09/2005

Overall study status
Completed

Last Edited
19/09/2008

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ZonMw: 945-04-311 2004/036 (projectnummer VUmc); NTR93

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

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

Secondary outcome measures
Key:
1. Costs
2. Operability of a recurrence
3. Surgical margins of the salvage laryngectomy
4. Quality of life

Overall study start date
01/02/2005

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

Age group
Adult

Sex
Both

Target number of participants
150

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)

Sponsor details
Van der Boechorststraat 7
Amsterdam
Netherlands
1081 BT

Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl/english/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration