Postoperative Accelerated RadioTherapy versus conventional radiotherapy in squamous cell head and neck cancer (POPART). A phase III randomised study.

No registrations found.

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

Summary

ID

NL-OMON21364

Source
NTR

Brief title
POPART, CKTO 2003-11

Health condition

Squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx or larynx

Sponsors and support

Primary sponsor: VU University Medical Center / Groningen University Medical Center Comprehensive Cancer Center Amsterdam (IKA)
Source(s) of monetary or material Support: Koningin Wilhelmina Fonds (KWF)

Intervention

Outcome measures

Primary outcome

Loco-regional control.

Secondary outcome

1. Distant metastases;

2. Disease free survival;

3. Overall survival;

4. Quality of life;

5. Acute morbidity,

6. Late morbidity;

7. Cost-effectiveness.

Study description

Background summary

N/A

Study objective

Test in a phase III randomised study whether an improvement of loco-regional control can be obtained with accelerated postoperative radiotherapy (66 Gy in 5 weeks) as compared to conventionally fractionated radiotherapy (66 Gy in 7 weeks) in patients who are at high or very high risk for loco-regional recurrence after primary surgery for squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx and/or larynx.

Intervention

Accelerated postoperative radiotherapy (66 Gy in 5 weeks) as compared to conventionally fractionated radiotherapy (66 Gy in 7 weeks).

Contacts

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Eligibility criteria

Inclusion criteria

1. Proper clinical evaluation must have been performed according to the national guidelines;

2. Histologically proven squamous cell carcinoma (WHO grade 1-3) of the oral cavity, oropharynx, hypopharynx or larynx (unknown primary excluded);

3. Primary surgery with curative intent
high risk for loco-regional recurrence, i.e. positive resection margins (< 1 mm) and/or lymph node metastases with extranodal spread;

4. Radiotherapy must start preferentially within 6 weeks but not later than 7 weeks after surgery;

5. Previously untreated patients (except the surgery);

6. Age > 18 years;

7. WHO performance status 0-2
patients of reproductive potential must agree to practice an effective contraceptive method;

8. Written informed consent.

Exclusion criteria

1. Macroscopic residual disease at the primary site and/or neck;

2. Distant metastases;

3. Previous malignancy except basal cell carcinoma of the skin or in situ carcinoma of the cervix or superficial bladder cancer (pTa);

4. Previous induction chemotherapy, concurrent or adjuvant chemotherapy.
pregnant or lactating;

5. Any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2003
Enrollment:	350
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-09-2005
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	NL272
NTR-old	NTR310
Other	: N/A
ISRCTN	ISRCTN72086307

Study results

Summary results
N/A