

Post-Operative Accelerated RadioTherapy versus conventional radiotherapy in squamous cell head and neck cancer: a phase III randomised study

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 20/12/2005	Overall study status Completed	☐ Protocol
Last Edited 28/01/2009	Condition category Cancer	☐ 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

Contact name

Prof J A Langendijk

Contact details

Groningen University Medical Centre
Head Department Radiotherapie
Hanzeplein 1
Groningen
Netherlands
9713 GZ
+31 (0)50 361 1190
j.a.langendijk@umcg.nl

Additional identifiers

Protocol serial number

NTR310; CKTO 2003-11

Study information

Scientific Title

Conventionally fractionated versus accelerated postoperative radiotherapy in squamous cell carcinoma of the head and neck (SCCHC): a phase III randomised study

Acronym

POPART

Study objectives

Test in a phase III randomised study whether an improvement of loco-regional control can be obtained with accelerated post-operative 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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local ethics committee

Primary study design

Interventional

Study design

Multicentre randomised active controlled parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Squamous cell carcinoma, oral cavity, oropharynx, hypopharynx, larynx

Interventions

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

Other joint sponsors:

1. University Medical Centre Groningen (UMCG) (Netherlands)
2. Integrated Cancer Centre Amsterdam (Integraal Kankercentrum Amsterdam [IKA]) (Netherlands)

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Loco-regional control.

Key secondary outcome(s)

1. Distant metastases
2. Disease free survival
3. Overall survival
4. Quality of life
5. Acute morbidity
6. Late morbidity
7. Cost-effectiveness

Completion date

01/01/2009

Eligibility**Key inclusion criteria**

1. Proper clinical evaluation must have been performed according to the national guidelines
2. Histologically proven squamous cell carcinoma (World Health Organisation [WHO] grade 1 - 3) of the oral cavity, oropharynx, hypopharynx or larynx (unknown primary excluded)
3. Primary surgery with curative intent
4. High risk for loco-regional recurrence, i.e. positive resection margins (less than 1 mm) and/or lymph node metastases with extranodal spread
5. Radiotherapy must start preferentially within 6 weeks but not later than 7 weeks after surgery
6. Previously untreated patients (except the surgery)
7. Age greater than 18 years, either sex
8. WHO performance status 0 - 2
9. Patients of reproductive potential must agree to practice an effective contraceptive method
10. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key 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
5. Pregnant or lactating

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

Date of first enrolment

01/12/2003

Date of final enrolment

01/01/2009

Locations

Countries of recruitment

Netherlands

Study participating centre

Groningen University Medical Centre

Groningen

Netherlands

9713 GZ

Sponsor information

Organisation

Vrije University Medical Centre (VUMC) (Netherlands)

ROR

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

Funder(s)

Funder type

Charity

Funder Name

The National Cancer Fund (Koningin Wilhelmina Fonds [KWF]) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration