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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 [_] Protocol
Registration date 20/12/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 28/01/2009	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Multicentre randomised active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Loco-regional control.

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

Overall study start date
01/12/2003

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

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
350

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)

Sponsor details

Van der Boechorststraat 7
Amsterdam
Netherlands
1081 BT

Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Charity

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