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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21364

Bron
NTR

Verkorte titel
POPART, CKTO 2003-11

Aandoening

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

Ondersteuning

Primaire sponsor: VU University Medical Center / Groningen University Medical Center Comprehensive Cancer Center Amsterdam (IKA)
Overige ondersteuning: Koningin Wilhelmina Fonds (KWF)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Loco-regional control.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2003
Aantal proefpersonen:	350
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL272
NTR-old	NTR310
Ander register	: N/A
ISRCTN	ISRCTN72086307

Resultaten

Samenvatting resultaten
N/A