NEW CLINICAL TRIAL OPEN FOR INCLUSION

PROTOCOL TITLE

A prospective randomized phase 2 study of dose and volume de-escalation radiotherapy with sentinel lymph nodes mapping for contralateral irradiation in unilaterally node positive head and neck squamous cell carcinomas (NCT04688528)

ALIAS	CTO NUMBER	SPONSOR
Semirahn	CTO25040UZL	UZ Leuven

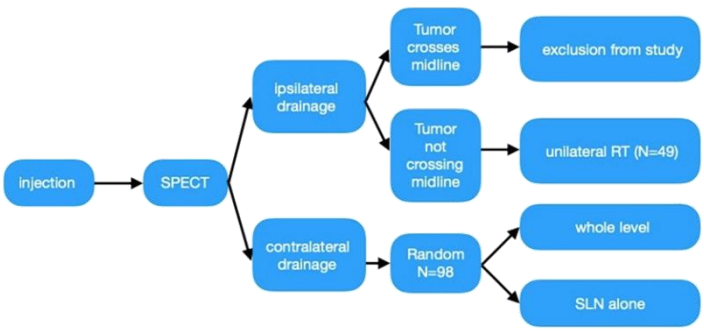
KEY INCLUSION AND EXCLUSION CRITERIA

Pathologically proven invasive HNSCC, including oral cavity, oropharynx (independently of HPV status), larynx or hypopharynx.
Primary treatment with radical radiotherapy with or without concurrent chemotherapy.
Tumor characteristics:

- cT-classification: T1(except T1 of glottis)-T4a (or, for p16+ oropharyngeal tumors classified cT4, if criteria are compatible with cT4a-stage of p16- tumors).
- cN-classification, as assessed by iodine contrasted CT (or MRI) and FDG-PET:
  - mandatorily cN0 contralaterally to the primary tumor (or on one side of the neck for midline primary tumors).
  - ipsilaterally positive, i.e. cN1, cN2a, cN2b, ipsilateral cN3b; or cN1 (TNM8) for oropharyngeal p16+ tumors.
- No distant metastasis.

DESIGN

- A total of 147 patients is expected across 9 Belgian centers
- Injection of 99mTc-nanocolloid at the 4 poles of the tumor (under general anesthesia if the tumor is not accessible trans-orally).
- SPECT/CT of head & neck region under radiotherapy mask.
- Identification of sentinel lymph node(s) on SPECT/CT images and on correlated CT-simulation images.
- The elective volume to be irradiated is individualized to the result of the SPECT/CT (i.e. « volume de-escalation »)



- In case of ipsilateral drainage only, primary tumor extension across the midline will drive the decision. Patients with tumor not crossing the midline will be treated unilaterally. If tumor crosses the midline, patients will be excluded from study and irradiated according to standard guidelines for safety reasons.
- In case of contralateral drainage, 98 patients will randomized between either sentinel lymph node only (SLN) or SLN-containing level elective irradiation.
- All patients will be treated to a reduced elective dose of 49 Gy instead of 54.25 (« dose de-escalation »)

ENDPOINTS

PRIMARY: 2-years contralateral regional control (cRC)
SECONDARY:

- Overall survival (OS), cancer specific survival (CSS) and loco-regional control (LRC) rates at 2 years;
- quality of life (QoL) at baseline, end of treatment (EOT) and 2, 4, 8, 12, 18 and 24 months post-EOT;
- in silico comparison of doses to OAR and subsequent NTCP variations.

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GRANT
Stichting tegen Kanker FAF-C/2018/1266