Organoids model in laryngeal cancer

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23214

Source
Nationaal Trial Register

Brief title
TBA

Health condition

laryngeal cancer, sentinel lymph node

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

We want to further develop and evaluate our patients’ specific ex vivo LC organoids in which at least 50% of the obtained tumor samples are viable and proliferating at week 2 and 6.

Secondary outcome

We will analyse differences in solidity of ex vivo LC organoids between primary and recurrent LC tissue.

Study description

Background summary

Despite intensive treatment, prognosis of laryngeal cancer (LC) remains poor. Five years overall survival is 60% and an accurate treatment is of paramount significance to improve overall survival. Most patients with LC will receive larynx preserving (chemo)radiation without knowing the sensitivity of the LC. Selecting LC with low (chemo)radiosensitivity could prevent unnecessary (chemo)radiation.
Organoids which are tumor-derived three-dimensional cancer stem cells that mimic in vivo tumor characteristics were explored and efficacy has been tested in our well-established collaboration with the UMCG departments of Biomedical Sciences of Cells & Systems/Radiation Oncology, Medical Oncology, Ear Nose Throat/Head and Neck Surgery, Pathology and Maxillofacial Surgery. Recently, the optimized organoids culture methodology for squamous esophageal cancers resulted in the parallel development of a culture methodology for organoids of head and neck squamous cell which was shown to be successful in six out of fourteen tumors. In this study we would like to develop and evaluate the efficacy of a solid ex vivo LC tumor model (= LC organoids) of patient derived LC tumor material by whole genome DNA sequencing. With solid LC organoids we would be able to test the effects of standard (chemo)radiation on self-renewal and regrowth potential of the LC stem cell derived organoids in future. Solid organoids predicting the patients (chemo)radiation response could lead to an improvement of LC treatment, by allowing selection of patients who will benefit from surgical treatment bypassing (chemo)radiation and as such improving survival and reducing side effects thereby increasing post-treatment quality of life.

Study objective

We hypothesize that of our patients specific ex vivo LC organoids at least 50% of obtained LC tumor samples are viable and proliferating at week 2 and 6.

Study design

During surgery

Intervention

Biopsies will be taken at the departments of Otolaryngology / Head and Neck Surgery or Maxillofacial Surgery of the University Medical Center Groningen. During routine biopsy or resection, additional biopsies of the tumor will be taken or additional tumor tissue (maximum 0.5 cm3) will be removed. The subjects will not undergo extra procedures in the course of the research: only routinely procedures are performed (i.e. endoscopic examination in the outpatient clinic or under general anaesthesia for tumor staging, resection of tumor by neck dissection, total laryngectomy). Organoids of the ex vivo model will be developed and tested in the Laboratory of Medical Oncology and Laboratory of Cell Biology / Radiation Oncology,

University Medical Center Groningen.

Contacts

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Eligibility criteria

Inclusion criteria

- proven carcinoma of the larynx
- > 18 yrs of age
- planned routine biopsy or planned surgical resection as part of standard diagnostic work-up or treatment
- expected tumor volume > 2 cm3
- informed consent

Exclusion criteria

- non-squamous cell carcinoma after definitive histological analysis

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2021
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	06-10-2020
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	NL8956
Other	METC Groningen : METC73814

Study results