Genomic Instability based analysis of drugable targets in Head and Neck Cancer:
Tumor tissue for an ex vivo pilot study

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if at least 50% of the obtained tumor samples will be viable and proliferating after 14 days (i.e. proliferation rate at day 14 is at least 50% of the proliferation rate at day 0), the ex vivo model will be considered as feasible

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Soft tissue neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON47568

Source
ToetsingOnline

Brief title
GIBADT-HNC: ex vivo pilot study

Condition

- Soft tissue neoplasms malignant and unspecified

Synonym
head and neck cancer, HNSCC

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: KWF/Alpe D□Huzes□Bas Mulder grant RUG 2013-5960;NWO VIDI grant 916-76062

Intervention

Keyword: ex vivo, head and neck cancer, pilot studie

Outcome measures

Primary outcome

viable tumor tissue after 6 days ex vivo culturing

Secondary outcome

not applicable

Study description

Background summary

Prognosis in head and neck cancer has not improved significantly and remains poor for patients with locally advanced disease, despite intensive treatment. We developed a method to determine the degree of genomic instability of tumors. Using mRNA expression patterns of 407 head and neck squamous cell carcinomas (HNSCC), we demonstrated that HNSCCs are highly instable compared to normal mucosa and that there is a wide range in genomic instability between tumors. In normal cells, a high degree of genomic instability results in apoptosis. We identified genes which overexpression is highly correlated with genomic instability. We hypothesize that overexpression of these genes is a coping strategy to survive genomic instability. Inhibition of these targets therefore may have a potent antitumor activity. We would like to evaluate the clinical relevance of these targets in head and neck cancer in an ex vivo model, using patient derived tumor tissue. Therefore feasibility of the ex vivo model should be tested in HNSCC.

Study objective

if at least 50% of the obtained tumor samples will be viable and proliferating after 14 days (i.e. proliferation rate at day 14 is at least 50% of the proliferation rate at day 0), the ex vivo model will be considered as feasible

Study design

prospective collection of fresh tumor tissue to test feasibility of an ex vivo tumor model

Study burden and risks

no significant additional burden or risks are to be expected when additional 0.5 cm3 tumor tissue is removed during routine surgical resection or staging endoscopy under general anaesthesia in which diagnostic biopsies are routinely taken.
Patients do not derive benefit prom participation in this study. We hope that this study contributes to development of new treatment strategies for future patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Strong suspicion of or proven carcinoma of the oral cavity, pharynx or 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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-09-2015
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	15-06-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO Date:	10-04-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-07-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL51862.042.15