Chromosomal instability as indicator for the treatment of progressive mucosal lesions of the oral cavity: a prospective study.

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The aim of this prospective study is the prevention of progression of premalignant lesions to invasive head and neck cancer by modifying the out-patient follow up and patient management.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON40192

Source
ToetsingOnline

Brief title
Treatment of mucosal lesions of the oral cavity using a cancerrisk-test

Condition

- Miscellaneous and site unspecified neoplasms benign
- Head and neck therapeutic procedures

Synonym
hyperkeratosis, hyperplasia, mild to moderate dysplasia, premalignant laesion.

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chromosomal instabillity, Fluorescence In Situ Hybridization, Loss of Heterozygostiy, low grade dysplasia

Outcome measures

Primary outcome

The primary goal of this prospective study is:

(1) Demonstrating the predictive value of the detection of CIN in premalignant lesions of the oral cavity by the use of FISH for the occurrence of progression to severe dysplasia /CIS or invasive carcinoma.

(2) The prevention of progression of premalignant lesions of the oral cavity to severe dysplasia / CIS or invasive carcinoma by the treatment of selected high-risk lesions.

Secondary outcome

The secondary objective of this study is as follows:

(3) Demonstrating the predictive value of the detection of LOH in premalignant lesions of the oral cavity by the use of DNA markers for the occurrence of progression to severe dysplasia / CIS or invasive carcinoma.

(4) Conducting a primary and secondary cost analysis.

Study description

Background summary

Summarized we can say that head and neck carcinomas despite improvements in therapy still have a poor prognosis with a 5-year survival of ~ 50%. Malignancies of the head and neck area are (almost) always preceded by precursorlesions. Treatment of these premalignant mucosal abnormalities is generally limited and not very inconvenient for the patient. If this precursor lesion remain untreated, it may develop into a malignancy of the head and neck. Extensive treatment will be necessary. This means loss of function of the mouth, eg chewing, speaking and swallowing.

Our hypothesis is that CIN detected by FISH is a reliable indicator for progression to malignancy. By intensifying the follow up and treatment in premalignant CIN lesions, the incidence of progression to invasive carcinoma is expected to be significantly reduced. If this hypothesis is justified, there will be a place for CIN detection as a risk indicator in the diagnostic work up of premalignant lesions in the head and neck.

Our second hypothesis is that LOH detected bij DNA markers is a reliable indicatior for progression to malignancy. By intensifying the outpatient clinic follow up and treatment in premalignant lesions, the incidence of progression to invasive carcinoma is expected to be significantly reduced. If this hypothesis is justified, there will be a place for CIN and LOH detection as a risk indicator in the diagnostic work up of premalignant lesions in the head and neck.

Study objective

The aim of this prospective study is the prevention of progression of premalignant lesions to invasive head and neck cancer by modifying the out-patient follow up and patient management.

Study design

This is an open randomised controlled trial with parallel groups.

Intervention

Fifty percent of patients with a CIN-positive lesion will be admitted to the ward for 1 day when they are treated, under general anesthesia, via an excision or CO2 laser evaporisation of the mucosal lesion of the oral cavity. Furthermore, all patients (CIN-positive and CIn-negative) are subjected to an intensified outpatient clinic follow up.

Study burden and risks

Burden:
If a subject is assigned to the intervention group, he will undergo a(n)

(extra) surgical procedure under general anesthesia to remove the mucosal lesion. Several risks apply to this procedure. General anesthesia may lead to nausea and vomiting after the procedure, or a sore throat from the ventilation tube. Rare cases of allergic reactions to medicines occur. The surgical procedure might cause an infection or a bleeding after surgery. Pain may occur. During 5 years subjects will be seen at the outpatient clinic, in total sixteen visits are scheduled. Physical examination of the head and neck region will be performed by an otorhinolaryngologist.

Benefit:
Because of close surveillance of subjects and treatment of CIN-positive lesions in the intervention group, a decrease in the frequency of malignant outgrowth will be expected. Therefore, subjects will have less chance to develop a malignancy at the head and neck region and extensive treatment or (lifelong) side effects of cancer treatment will be prevented.

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

Subject has a minimal age of 18 years
premalignant laesion of the oropharynx, classified as hyperkeratosis, hyperplasia, mild or moderate dysplasia
Singned informed consent form

Exclusion criteria

Prior malignancy or laesion classified as severe dysplasia or carcinoma in situ at the same anatomical location of the oropharynx.
Prior treatment of laesions at the same anatomical location of the oropharynx (ie radiotherapy)
Insufficient biopsy material to perform a FISH analysis.
Pregnancy, based on physical load (ie extra anesthaesia)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	374
Type:	Anticipated

Ethics review

Approved WMO Date:	31-12-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT02238574
CCMO	NL46343.068.13