

# Electrochemotherapy in head and neck cancer patients

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Completed
<b>Health condition type</b>	Respiratory and mediastinal neoplasms malignant and unspecified
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON36446

### Source

ToetsingOnline

### Brief title

Electrochemotherapy in head and neck cancer patients

### Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Head and neck therapeutic procedures

### Synonym

head and neck cancer

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** electroporation, head and neck cancer

## Outcome measures

### Primary outcome

Treatment response

### Secondary outcome

Adverse effects and serious adverse events and quality of life

## Study description

### Background summary

Na eerdere behandelingen in het hoofd-halsgebied kunnen bij de behandeling van een nieuwe/recidu/recidief tumor geen reguliere therapeutische opties meer voorhanden zijn. Electrochemotherapie is een relatief nieuwe behandelingsmodaliteit die soms nog wel mogelijk is.

### Study objective

The primary objective of this study is to determine the response rate of electrochemotherapy in head and neck cancer. Secondary objectives are to monitor local and systemic side effects and adverse events and to determine quality of life before and after electrochemotherapy

### Study design

Prospective, monocenter open-label study of 10 patients to define the treatment response of electrochemotherapy in end-stage head and neck cancer patients.

### Intervention

Intratumoral or intravenous application of bleomycin followed by electroporation in which an applicator with needle electrodes are repeatedly applied to the entire tumor with margins.

### Study burden and risks

Burden to the patient consist of hospital admission and treatment under general anesthesia. Risks are related to reported adverse effects, e.g. pain, bleeding, oedema and necrosis.

## Contacts

### Public

Vrije Universiteit Medisch Centrum

De Boelelaan 1117

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Biopsy confirmed malignancy of mucosa or skin

Accessibility of the entire tumor (with 0.5 cm margins) for the applicator with electrode array all directions

Creatinine level < 150 µmol/l

## Exclusion criteria

Tumors that involve a 50% or greater encasement of a blood vessel as measured by MRI or CT scan

Tumors having bone invasion

Hypersensitivity to Bleomycin

Subjects who have received or will exceed a total lifetime dose of Bleomycin greater than 400.000 IUg/m<sup>2</sup>

Subjects deemed unsuitable for general anesthesia and local anesthesia is not possible.

Subjects with pulmonary fibrosis.

Subjects with indwelling cardiac pacemakers who cannot tolerate a period with pacemaker turned off

Subjects with a history of uncontrolled cardiac arrhythmia

Women who are pregnant, or are nursing

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Completed

Start date (anticipated): 01-05-2011

Enrollment: 10

Type: Actual

### Medical products/devices used

Generic name: electroporation equipment Cliniporator

Registration: Yes - CE intended use

## Ethics review

Approved WMO

Date: 17-01-2011

Application type: First submission

Review commission: METC Amsterdam UMC

## 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	NL34661.029.10