Electrochemotherapy in head and neck cancer patients

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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...

Ethical review	Approved WMO
Status	Completed
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	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 intraveneous application of bleomycin fllowed 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

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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/m2
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