Image guided surgery for margin assessment of squamous cell carcinoma during Mohs micrographic surgery: a phase I proof of concept study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23751

Source
NTR

Brief title
IG-MMS

Health condition

Cutaneous squamous cell carcinoma

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

- Macroscopic fluorescent signal levels (TBR) and tracer distribution observed by NIR

fluorescence imaging using the intraoperative in vivo imaging as well as the ex vivo backtable
imaging;
- Quantification of fluorescent signals using MDSFR/SFF spectroscopy;
- Standard histopathological assessment (i.e. haematoxylin and eosin staining) to correlate fluorescent and non-fluorescent areas detected in vivo with histology using surgical specimen;

Secondary outcome

- Histopathologic examinations related to ex vivo EGFR expression and cetuximab-IRDyeCW800 distribution.
- Quantification of the cetuximab-800CW optoacoustic signal and the tracer distribution observed by multispectral optoacoustic imaging using the MSOT Acuity Echo in vivo.

Study description

Background summary

The gold standard of treatment in non-melanoma skin cancer (NMSC) is surgical excision, for which micrographic surgery techniques are developed to ensure the complete removal of tumor tissue, while maximizing normal tissue conservation. Mohs Micrographic Surgery (MMS) is recommended for high-risk and recurrent basal cell carcinoma, cutaneous squamous cell carcinoma (cSCC) and other uncommon skin tumors. Although MMS is beneficial for precise margin assessment, it is time-consuming and labor-intensive. The preparation usually takes 20 to 60 minutes per excision, during which the patient waits, and the entire cycle is repeated until a tumor free plane is achieved. Moreover, the size of the tumor limits the indication for MMS. There is need for an instrument that can reliably support tumor excision with 100% margin control in a ‘real-time’ manner, irrespectively to the size and origin of the tumor.

Molecular fluorescence guided surgery enables the visualization of targeted tumor-specific biomarkers by using fluorescence, thereby enhancing the contrast between tumor and normal tissue. The objective of this feasibility study is to determine if the intravenously administered conjugate cetixumab-IRDye800CW can be used for intraoperative margin assessment during MMS in patients with cutaneous squamous cell carcinoma.

Study objective

Image guided surgery using cetuximab-IRDye800CW enables margin assessment during Mohs micrographic surgery.

Study design

The primary objectives of this study are studied during and immediately after surgery

Intervention

Intravenous injection of an unlabeled predose (cetuximab) and cetuximab-IRDye800CW two days prior to surgery. During surgery, fluorescence imaging will be performed.

Contacts

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Eligibility criteria

Inclusion criteria

1) Biopsy confirmed diagnosis of cSCC and scheduled to undergo surgical resection using MMS;
2) Age ≥ 18 years;
3) Written informed consent;
4) Mentally competent person showing adequate potential for follow-up;

For female subjects who are of childbearing potential, are premenopausal with intact reproductive organs or are less than 2 years post-menopausal:
5) A negative serum or urine pregnancy test prior to receiving the tracer.
6) Willing to ensure that she or her partner uses effective contraception during the trial and for 6 months thereafter.

Exclusion criteria

1) Medical or psychiatric conditions that compromise the patient’s ability to give informed consent;

2) Concurrent uncontrolled medical conditions.
3) Received an investigational drug within 30 days prior to the dose of cetuximab-IRDye800CW;
4) Tumors at sites of which the surgeon would assess that in vivo imaging would not be feasible;
5) Had within 6 months prior to enrollment: myocardial infarction, cerebrovascular accident, uncontrolled cardiac heart failure, significant liver disease, unstable angina;
6) Inadequately controlled hypertension with or without current antihypertensive medications;
7) History of infusion reactions to cetuximab or other monoclonal antibody therapies
8) Evidence of QT prolongation on pretreatment ECG (greater than 440 ms in males or greater than 450 ms in females);
9) Patients receiving Class IA (quinidine, procainamide) or Class III (dofetilide, amiodarone, sotalol) antiarrhythmic agents;
10) Magnesium, potassium and calcium deviations that might lead to cardiac rhythm (grade II or higher deviations by CTCAE).
11) Life expectancy < 26 weeks;
12) Karnofsky performance status < 70%.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	14-07-2019
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	25-06-2019
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	NL7828
Other	METC UMCG : METC 2019/183

Study results