The use of handheld reflectance confocal microscopy in the surgical treamtent of lentigo maligna

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22810

Source
Nationaal Trial Register

Brief title
LM-DARE

Health condition

Lentigo maligna
Reflectance confocal microscopy
Diagnostic accuracy

Sponsors and support

Primary sponsor: Netherlands Cancer Institute
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

To determine the diagnostic accuracy of HH-RCM in the presurgical margin delineation for

primary and recurrent LM in the head and neck treated by conventional surgical excision.

Secondary outcome

i. To evaluate the influence of HH-RCM on the surgical management of LM.

ii. To determine the long-term effect of HH-RCM assisted margin delineation on treatment-failure, defined by histopathological confirmed recurrences and/or the development of invasive melanoma.

i. To evaluate patient satisfaction with the use of HH-RCM in the management of LM.

Study description

Background summary

Rationale: Lentigo maligna (LM) is a melanoma in situ with a predilection for the head and neck. Treatment is aimed at preventing progression into lentigo maligna melanoma (LMM), which has the potential to metastasize. Currently the incidence of both LM and LMM are increasing at a greater rate than the other melanoma subtypes. Due to lesions size and localization in the head and neck, only a limited portion of the tumor is often sampled to confirm the diagnose. Consequently, there is a risk of missing an invasive component (i.e. sampling error), and surgical treatment remains the standard of care as it allows complete histological assessment. The current guideline recommend surgical margin of 5mm is often insufficient due to subclinical extension of LM. If we could accurately determine the optimal surgical margins of LM, we may be able to avoid local recurrences and/or progression. Handheld reflectance confocal microscopy (HH-RCM) is a noninvasive imaging technique that allows the in vivo visualization of cutaneous structures at a cellular-level. Past studies have shown that RCM is well suited to differentiate LM from other pigmented macules in the head and neck, as well as detect subclinical LM. As a result, HH-RCM could potentially offer a non-invasive tool of in vivo presurgical margin delineation.

Objective: The aim of this study is to evaluate the efficacy of HH-RCM in the presurgical margin delineation for LM treated by conventional surgical excision.

Study design: A single-center, prospective, diagnostic accuracy, cohort study.

Study population: Sixty-one consecutive patients with histologically confirmed primary or recurrent LM in the head and neck.

Main study parameters/endpoints: Frequency of tumor-free margins, and accuracy (e.g. sensitivity, specificity) of the HH-RCM-determined margins, as well as the frequency of treatment failure, defined by a histologically confirmed recurrence or progression into LMM.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participating subjects will not receive any clinical relevant delay in treatment or miss out of standard of care. There will be one additional visit to the Dermatology outpatient clinic of the NKI compared to standard of care. The HH-RCM diagnostic procedure is non-invasive, painless and no side effects have been reported. The burden due to study requirements is minimal. All study patients will receive surgical treatment with the 5mm guideline recommend margin, in addition to the possibility of extended margins following HH-RCM delineation. Through this study we hope to provide personalized surgical margins, since the guideline recommended surgical margin is often insufficient. The potential added benefit could the decreased risk of incomplete excisions and recurrence rates, with the possibility of overtreatment (i.e. false positives).

Study objective

The aim of this study is to evaluate the efficacy of HH-RCM in the presurgical margin delineation for LM treated by conventional surgical excision.

Study design

Short-term: The diagnostic outcome of presurgical HH-RCM -assisted margin delineation. This outcome will be evaluated by assessing the frequency of tumor-free margins (including minimal free margin in mm) as reported on in the final pathology by a board-certified pathologist.

Long-term: Frequency of treatment failure, defined by a histologically confirmed recurrence or progression into invasive melanoma in the 2-year window of study follow-up, in addition to regular follow-up for a total of 5 years

Intervention

Presurgical margin delineation with handheld reflectance confocal microscopy

Contacts

Public
Yannick Elshot
[default]
The Netherlands
Scientific
Yannick Elshot
[default]
The Netherlands

Eligibility criteria

Inclusion criteria

i. Patients with histologically confirmed primary LM.

ii. Patients with histologically confirmed recurrent LM, defined by a clinical recurrence within 10mm from the previously treated area following (non-)surgical treatment ¡Ý 12 months ago.

iii. Lesion localization in the head and neck (i.e. supraclavicular/above the 7th cervical vertebrae).

iv. Patients eligible for surgical excision.

v. Anatomic localization of the lesion allows evaluation by HH-RCM.

vi. Patient age ¡Ý 18 years and is willing and able to comply with the study requirements and give written informed consent.

Exclusion criteria

i. Patients with histologically confirmed LMM according to the WHO 2011 criteria (WHO ICD-O-3 8742/3) as assessed by standard of care.

ii. Patients with incomplete excised LM or histological confirmed recurrence within < 12 months following (non-)surgical treatment.

iii. Lesion localization outside the head and neck (i.e. infraclavicular/below the 7th cervical vertebrae).

iv. Patients ineligible for surgical excision (e.g. cosmetic/functional ramifications, co-morbidity, patient refusal).

v. Lesion localization is not accessible by HH-RCM.

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):	01-09-2018
Enrollment:	61
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL7062
NTR-old	NTR7300

Register
Other

ID
: N18LMD

Study results