Diagnosis of basal cell carcinoma in the head and neck by dermoscopy and handheld reflectance confocal microscopy.

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Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	Skin neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON27500

Source
NTR

Brief title
BCC-COMI

Condition

- Skin neoplasms malignant and unspecified

Health condition

basal cell carcinoma, diagnostics, dermoscopy, confocal microscopy, rcm

Research involving
Human

Sponsors and support

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

Intervention

- Medical device

Explanation

Outcome measures

Primary outcome

1. The diagnostic accuracy of dermoscopy and HH-RCM in diagnosing and subtyping (Table 1) of BCC in the head and neck, compared to the current diagnostic reference standard (3mm punch biopsy).
2. Rate of over- and understaging of BCC subtypes in the head and neck by dermoscopy (index), HH-RCM (index), and punch biopsy (control) compared to the outcome of the final excisional specimen (reference standard).

Secondary outcome

1. Reliability of naked-eye examination in the diagnosing and subtyping of BCC in the head and neck.
2. Diagnostic value of established dermoscopic and RCM criteria in the differentiation of BCC subtypes in the head and neck.
3. Inter- and intraobserver agreement of the dermoscopic and HH-RCM criteria, diagnosis and subtyping of BCC.

Study description

Background summary

The increasing incidence of basal cell carcinoma (BCC) in the Netherlands has become a burden on healthcare system due to the associated costs in diagnosing, treatment, and follow-up of BCC patients. As the majority of BCCs requiring surgical treatment are localized in the head and neck, accurate presurgical subtyping is essential.The use of dermoscopy has been shown to significantly increase the accuracy of diagnosing BCCs, nevertheless, punch biopsy remains the reference standard due to the limited accuracy of BCC subtyping purely based on the clinical diagnosis. Even so, there is a substantial discordance between biopsy and excisional specimens where in 15% of the cases a more aggressive BCC subtype is found following excision. Reflectance confocal microscopy (RCM) is a noninvasive imaging

technique that allows the in vivo visualization of cutaneous structures at a cellular-level, with an estimated sensitivity and specificity of 97% and 93% respectfully in diagnosing BCC. A handheld-RCM (HH-RCM) device (VivaScope®3000; CaliberID) was introduced allowing for more rapid evaluation and accessibility to the more concave areas in the head and neck (i.e. nose, periorbital and ears), while retaining comparable accuracy compared to conventional RCM. Several criteria were described positively correlating with the diagnosis of BCCs, however few studies have described criteria to differentiate between the different BCC subtypes. Our primary objectives are to: (1) To determine the diagnostic value of the addition of HH-RCM to dermoscopy in the management of BCC in the head and neck, defined by an significant increase in diagnostic accuracy in the diagnosing/subtyping of BCC. (2) Compare the diagnostic accuracy of dermoscopy and HH-RCM to the current diagnostic reference standard (punch biopsy).

Study objective

Our primary objectives are to determine the diagnostic accuracy of handheld RCM in the diagnosing and subtyping of BCC in the head and neck compared to punch biopsy, and evaluate the associated rate of over- and understaging of BCC subtypes. In addition, we will evaluate the reliability of naked-eye examination and the diagnostic significance of established dermoscopic and RCM criteria in the differentiation of BCC subtypes in the head and neck

Study design

This study was designed as a single-center, prospective, paired cross-sectional cohort study, conducted at the Netherlands Cancer Institute (NKI) (Amsterdam).

Intervention

Reflection confocal microscopy

Study burden and risks

"Participating subjects will not receive any clinical relevant delay in treatment or miss out of any standard of care and follow-up. There will be no additional visits to the outpatient clinic of Dermatology of the NKI compared to regular standard of care as study assessment will take place during the standard follow-up visits. Local side effects of routine invasive procedures in this study (punch biopsy and surgical excision) include erythema (often 1-2 weeks), pain (common 1 day), local swelling (often 1-3 days), abnormal scar formation (rare), hypo- and or hyperpigmentation (rare) and wound infection (rare). The RCM diagnostic procedure is non-invasive, painless and no side effects have been reported. There are no associated systemic side effects with any of the involved procedures. The burden due to study requirements is minimal. The RCM imaging will not interfere with the standard of care. "

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

1. Patients with suspected primary BCC on naked-eye examination as assessed by an experienced board-certified dermatologist.
2. Lesion localization in the head and neck (i.e. supraclavicular/above the 7th cervical vertebrae) with an indication for surgical treatment.
3. Anatomic localization of the lesion allows evaluation by HH-RCM and dermoscopy.
4. Patient age ¡Ý 18 years and is willing and able to comply with the study requirements and give written informed consent

Exclusion criteria

1. Recurrent BCC, defined as a suspected BCC localized within 5mm from the site of previously surgically or non-surgically treated BCC.
2. Suspected BCC localized outside the head and neck (i.e. infraclavicular/below the 7th cervical vertebrae).
3. Anatomical localization of lesion not accessible by HH-RCM or dermoscopic imaging.
4. Patients with genetic syndromes with increased risk of developing BCCs (e.g. Gorlin-Goltz, xeroderma pigmentosa).
5. Patients being treated by immunosuppressive medication.
6. Lesions on previously radiated skin.
7. Patients not eligible for surgical excision due to co-morbidity/ patient refusal.

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-04-2017
Enrollment:	258
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	18-01-2017
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	NL6004
NTR-old	NTR6502
Other	Interne code : N17BCC

Study results