Treatment of basal cell carcinoma using a one-stop-shop with reflectance confocal microscopy: a randomized controlled multicenter trial

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Primary: to compare the OSS concept with RCM in the surgical treatment of BCCs with current standard of care.Secondary: to assess the accuracy (sensitivity and specificity) of diagnosing BCC by comparing RCM with punch biopsy as diagnostic tools....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON40630

Source
ToetsingOnline

Brief title
Basal cell carcinoma one-stop-shop (B-OSS)

Condition

- Skin neoplasms malignant and unspecified

Synonym
Skin cancer; BCC

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: Basel cell carcinoma, One-stop-shop, Reflectance confocal microscopy

Outcome measures

Primary outcome

Compare the OSS concept with RCM in the surgical treatment of BCCs with current standard of care, by assessing incomplete surgical excision on the final pathology report, defined by residual histopathological BCC features in HE stained sections of surgically excised specimen.

Secondary outcome

To assess the accuracy (sensitivity and specificity) of diagnosing BCC by comparing RCM with punch biopsy as diagnostic tools.

To assess the accuracy (sensitivity and specificity) of BCC subtyping by comparing RCM diagnosis, including inter- and intra-observer agreement, with final pathology report.

To compare the following items of the OSS concept with RCM in the surgical treatment of BCCs with current standard of care: 1. patient satisfaction of the RCM OSS concept for the surgical treatment of BCCs. 2. throughput time, defined by the time between arrival at consultation until end of surgical treatment at our outpatient clinic.

Study description

Background summary

Basal cell carcinoma (BCC) is the most prevalent skin cancer, and its prevalence is increasing. Histological analysis of punch biopsy remains the golden standard to confirm the clinical diagnosis of BCCs and dividing subtypes. However, due to the rising incidence of BCC there is a need for more efficient, non-invasive methods to diagnose BCCs. The use of real-time in vivo reflectance confocal microscopy (RCM) to diagnose BCCs has proven successful to address this need. Various studies have demonstrated that RCM is safe and accurate (sensitivity and specificity) to diagnose BCCs. Reported sensitivity and specificity for RCM in diagnosing BCC range from 83.9%-91.6% and 95.7%-97%, respectively. Furthermore, Peppelman et al. and Longo et al. recently reported on RCM features that might classify between nodular, micronodular, superficial and infiltrative subtypes of BCC. Incorporating RCM as non-invasive diagnostic tool in a BCC one-stop-shop (OSS) concept for lesions suitable for conventional surgical excision, in concordance with current Dutch guidelines, might reduce time between clinical diagnosis and treatment, administrative workload and costs. One-stop-shop implies that at the day of the initial outpatient clinic consultation, the diagnosis and treatment both take place. Surgical treatment of BCCs is generally performed under local anesthesia, which makes it suitable for an OSS approach.

Study objective

Primary: to compare the OSS concept with RCM in the surgical treatment of BCCs with current standard of care.
Secondary: to assess the accuracy (sensitivity and specificity) of diagnosing BCC by comparing RCM with punch biopsy as diagnostic tools.
Third: to assess the accuracy (sensitivity and specificity) of BCC subtyping by comparing RCM diagnosis, including inter- and intra-observer agreement, with final pathology report.
Fourth: to compare the following items of the OSS concept with RCM in the surgical treatment of BCCs with current standard of care: 1. patient satisfaction of the RCM OSS concept for the surgical treatment of BCCs. 2. throughput time, defined by the time between arrival at consultation until end of surgical treatment at our outpatient clinic.

Study design

Prospective non-inferiority, randomized controlled trial

Intervention

I Study group: clinically suspected new primary BCC lesion will be diagnosed and divided into subtypes using RCM imaging (Vivascope 1500; Lucid Technologies, Henrietta, NY, USA) according to a standardized protocol. After the diagnosis, excision of the BCC lesion with adequate margins will be performed on the same day at the Department of Dermatology according to the

one-stop-shop concept. Clinically suspected primary BCCs that are not confirmed by RCM will also receive surgical treatment with a margin of 3mm.

II Control group: clinically suspected new primary BCC lesion will be diagnosed and divided into subtypes according to current standard of care. A conventional 3mm punch biopsy will be performed in the most elevated part of the lesion using local anesthetics (1% xylocaine/adrenaline). Biopsy specimen will be analyzed by a pathologist (within 2 weeks). After the diagnosis, excision of the BCC lesion with adequate margins will be performed within the following 4 weeks according to current standard of care. Clinically suspected primary BCCs that are not confirmed by punch biopsy will also receive surgical treatment with a margin of 3mm.

Study burden and risks

Subjects participating in the study will be informed and will have to provide written informed consent prior to enrollment. Study participation will not result in additional follow-up visits other than clinically required 3 months post-operative.
Real-time in vivo RCM uses a confocal microscope to noninvasively image a thin surface of the skin at high resolution directly without the need for invasive biopsies. The diagnostic procedure itself is painless and no side effects have been reported. Outcome measures involve routinely processed surgical specimen after excision, patient satisfaction, calculation of throughput time and analyzing diagnostic accuracy of the RCM procedure in subtyping BCC lesions. All together the burden due to the study is minimal. Possible inconvenience for participating patients in the study group include that specific features for BCC subtyping are still being established. Therefore a potential side effect for those patients may include: less accurate subtyping of BCCs resulting in less adequate surgical margins. At the same time, RCM imaging may be of additional value in scanning the complete lesion, which potentially prevents missing a more aggressive part of a tumor in contrast to a biopsy.
Thus there is a potential benefit for the participating subject, namely non-invasive confirmation of clinical suspected BCC lesion followed by direct surgical treatment. Considering the relatively quick and simple procedure, non-invasiveness of diagnostic method, and the one-stop shop concept of diagnosing and treating BCC at the same consultation, the balance between burden, possible side effects and prospect for improvement might be very favorable.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Patients with clinically suspected new primary BCC as assessed by an experienced board certified dermatologist
* Patients seen at the outpatient clinic before 12.00 AM will be eligible to participate
* Patient is willing and able to give written informed consent
* Age >=18
* BCC lesion is suitable for conventional surgical excision under local anesthetics
* BCC lesion is present since at least 1 month

Exclusion criteria

* BCC lesion in a high-risk location of the face (H-zone and ears)
* Contra-indication for conventional surgical excision (primary surgical closure seems not achievable)
* Recurrent BCC lesion (BCC that has been previously unsuccessfully treated)
* Macroscopic ulcerating BCC lesions (not feasible for RCM analysis due to technical reasons)
* Patients with basal cell nevus syndrome
* Patients treated with hedgehog inhibitor medication

* Patients with a history of hypersensitivity to and/or allergy to local anesthesia
* Unavailability within the following 6 weeks (for example due to holiday or sports)
* Patients not competent to understand what the procedures involved

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-02-2015
Enrollment:	76
Type:	Actual

Medical products/devices used

Generic name:	VivaScope® 1500;reflectance confocal microscopy
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	01-10-2014
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	NL50112.018.14