One-stop-shop Study for Treatment of Basal Cell Carcinoma Using Reflectance Confocal Microscopy

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One-stop-shop concept, using real-time in vivo reflectance confocal microscopy as diagnostic tool is non-inferior to standard of care in the surgical management of new primary basal cell carcinoma

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21856

Bron
NTR

Verkorte titel
B-OSS

Aandoening

Basal cell carcinoma (BCC)

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC) Amsterdam
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Comparison between one stop shop using reflectance confocal microscopy in the surgical treatment of BCC and current standard of care using punch biopsy, by assessing incomplete surgical excision on the final pathology report.

Toelichting onderzoek

Achtergrond van het onderzoek

Basal cell carcinoma (BCC) is the most common cancer diagnosed in white populations worldwide. The rising incidence of BCCs is becoming a major worldwide public health problem (1,11). Between 1973 and 2009, the European standardized rate quadrupled from 40 to 165 per 100,000 person-years for men and from 34 to 157 for women, most probably as a result of more intensive UV exposure (12). This is supported by previous published epidemiological literature indicating that ultraviolet radiation is an important risk factor for BCC with a significant increase among outdoor workers (13,14). Despite the low mortality from BCC, multiple and recurring tumors confer a high morbidity and considerable burden for health care providers and health budgets. Although BCC does not seem to have a high effect on patients' quality of life, patients suffering from BCC are definitely interested in efficacy, low recurrence rates and cosmetic outcome of their therapies.(15). Meanwhile resources available at hospitals have not increased proportionally and therefore optimizing effectiveness of present treatment modalities in daily dermatologic practice is mandatory (16).

Clinically, BCC are characterized by small, translucent, or pearly papules, with raised teleangiectatic edges (17) . Most of the BCC occur in sun-exposed skin of the head and neck area (18,19). Sensitivity and positive predictive value for the clinical diagnosing of BCC by dermatologists has been reported to be 95.4% and 85.9%, respectively (20). However, dividing between BCC subtypes is not always possible upon clinical assessment. To date, histological analysis of punch biopsy remains the golden standard to confirm the clinical diagnosis of BCCs and dividing between the following subtypes: nodular (nBCC), micronodular (mnBCC), infiltrating (iBCC) and superficial (sBCC) (10). Of those, nBCC and sBCC have a less aggressive growth pattern in comparison to mnBCC and iBCC. Additionally, mixed type BCC (mtBCC) can be defined as a combination of subtypes and are frequently composed of aggressive subtypes (21). Surgical excision remains the standard of treatment, with Mohs micrographic surgery typically utilized for high-risk lesions (22). Based upon the histological growth pattern, BCC are surgically removed with a margin of either 3mm (nBCC and sBCC) or 5mm (mnBCC, iBCC) in accordance with current Dutch guidelines (10).

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(2-6). Reported sensitivity and specificity for RCM in diagnosing BCC range from 83%-100% and 79%-97%, respectively (7). Furthermore, Peppelman et al. and Longo et al. recently reported on RCM features that might divide between nodular, micronodular, superficial and infiltrative subtypes of BCC (8,9).

In 2012, van der Geer et al reported on the feasibility of a one-stop-shop (OSS) concept for the treatment of skin cancer patients (23). One-stop-shop implies that at the day of the initial outpatient clinic consultation, diagnosis and treatment plan both take place. In their study, pre-operative frozen section histology was used to confirm BCC diagnosis and subtype. The mean throughput time was 4 hours and 7 min, no complications were observed, and patient satisfaction was high (23). Incorporating RCM as non-invasive diagnostic tool in a BCC OSS concept for lesions suitable for conventional surgical excision might further reduce time between clinical diagnosis and treatment, administrative workload and costs.

The aim of our study is to assess the efficacy and safety of the one-stop-shop concept, using real-time in vivo reflectance confocal microscopy (Vivascope 1500; Lucid Technologies, Henrietta, NY, USA) as diagnostic tool, prior to surgical management of new primary BCCs, of all subtypes, in the general population.

Doel van het onderzoek

One-stop-shop concept, using real-time in vivo reflectance confocal microscopy as diagnostic tool is non-inferior to standard of care in the surgical management of new primary basal cell carcinoma

Onderzoeksopzet

Primary: Comparison between one stop shop using reflectance confocal microscopy in the surgical treatment of BCC and current standard of care using punch biopsy, by assessing incomplete surgical excision on the final pathology report. [Time Frame: Within the first week after surgical excision of suspected BCC lesion]
Secondary: 1. Comparison of the diagnostic accuracy (sensitivity and specificity) between RCM and punch biopsy in both diagnosing and subtyping BCCs [Time Frame: Within the first week after surgical excision of suspected BCC lesion]
2. Comparison of patient satisfaction between study group and standard of care (control) group by using a standardized web-based questionnaire for patient reported outcome in the management of skin diseases (www.huidvragen.info) [Time Frame: As assessed at the post-operative visit 3 months after surgical excision]

3. Comparison of throughput time, defined by the time between arrival at consultation until end of surgical treatment at our outpatient clinic, between study group and standard of care (control) group. [Time Frame: As assessed at the post-operative visit 3 months after surgical excision]

Onderzoeksproduct en/of interventie

Conventional surgical excision under local anesthetics

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with clinically suspected new primary BCC as assessed by an experienced board certified

dermatologist

Patients seen at the outpatient clinic before 12h00 AM will be eligible to participate

Patient is willing and able to give written informed consent

BCC lesion is suitable for conventional surgical excision under local anesthetics

BCC lesion is present since at least 1 month

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 a history of allergy to local anesthesia

Unavailability within the following 6 weeks (for example due to holiday or sports)

Patients not competent to understand the procedures involved

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	03-02-2015
Aantal proefpersonen:	76
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-08-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5165
NTR-old	NTR5305
Ander register	NCT02285790 : Clinicaltrials.gov

Resultaten

Samenvatting resultaten

Kadouch et al. Treatment of basal cell carcinoma using a one-stop-shop with reflectance

confocal
microscopy: study design and protocol of a randomized controlled multicenter trial . JMIR Res Protoc (in press). doi:10.2196/resprot.4303 http://dx.doi.org/10.2196/resprot.4303