TREATMENT OF BASAL CELL CARCINOMA USING A ONE-STOP-SHOP WITH REFLECTANCE
CONFOCAL MICROSCOPY: STUDY DESIGN AND PROTOCOL OF A RANDOMIZED CONTROLLED
MULTICENTER TRIAL.

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ABSTRACT
BACKGROUND: Basal cell carcinoma (BCC) is the most common cancer diagnosed in white populations
worldwide. The rising incidence of BCC is becoming a major worldwide public health problem. Therefore,
there is a need for more efficient management.

OBJECTIVE: The aim of this research is to assess the efficacy and safety of a one-stop-shop (OSS)
concept, using real-time in vivo reflectance confocal microscopy (RCM) (Vivascope 1500; Lucid
Technologies, Henrietta, NY, USA) as a diagnostic tool, prior to surgical management of new primary
BCCs. METHODS: This is a prospective non-inferiority multi-center RCT designed to compare the "OSS
concept using RCM" to current standards of care in diagnosing and treating clinically suspected BCC.
Patients ≥ 18 years attending our outpatient clinic at the Department of Dermatology, Academic Medical
Center, University of Amsterdam, and the Department of Dermatology, the Netherlands Cancer
Institute-Antoni van Leeuwenhoek Hospital (Amsterdam, The Netherlands) with a clinically suspected
new primary BCC lesion will be considered for enrollment using predefined inclusion and exclusion
criteria, and will be randomly allocated to the experimental or control group. The main outcome
parameter is the assessment of incomplete surgical excision margins on the final pathology report of
confirmed BCC lesions (either by punch biopsy or RCM imaging). Other outcome measures include
diagnostic accuracy (sensitivity and specificity) of RCM for diagnosing BCC and dividing between
subtypes, and throughput time. Patient satisfaction data will be collected postoperatively after 3 months
during routine follow-up. RESULTS: This research is investigator-initiated and received ethics approval.
Patient recruitment started in February 2015, and we expect all study-related activities to be completed
by fall 2015.

CONCLUSIONS: This RCT is the first to examine an OSS concept using RCM for diagnosing and treating
clinically suspected BCC lesions. Results of this research are expected to have applications in
evidence-based practice for the increasing number of patients suffering from BCC and possibly lead to a
more efficient disease management strategy.

TRIAL REGISTRATION: ClinicalTrials.gov: NCT02285790;
https://clinicaltrial.gov/ct2/show/NCT02285790 (Archived by WebCite at
http://www.webcitation.org/6b2LfDKWu ).