

Medical > In Vivo > Non-Melanoma Skin Cancer Research > Basal Cell Carcinoma

35

Diagnosis of Basal Cell Carcinoma by Reflectance Confocal Microscopy: Study Design and Protocol of a Randomized Controlled Multicenter Trial.

Peppelman M, Nguyen KP, Alkemade HA, Maessen-Visch B, Hendriks JC, van Erp PE, Adang EM, Gerritsen MJ. *JMIR Res Protoc.* 2016 Jun 30;5(2):e114. doi: 10.2196/resprot.5757.

ABSTRACT

BACKGROUND: Skin cancer, including basal cell carcinoma (BCC), has become a major health care problem. The limitations of a punch biopsy (at present the gold standard) as diagnostic method together with the increasing incidence of skin cancer point out the need for more accurate, cost-effective, and patient friendly diagnostic tools. In vivo reflectance confocal microscopy (RCM) is a noninvasive imaging technique that has great potential for skin cancer diagnosis. **OBJECTIVE:** To investigate whether in vivo RCM can correctly identify the subtype of BCC and to determine the cost-effectiveness of RCM compared with punch biopsy (usual care). **STUDY DESIGN:** Randomized controlled multicenter trial. **METHODS:** On the basis of 80% power and an alpha of 0.05, 329 patients with lesions clinically suspicious for BCC will be included in this study. Patients will be randomized for RCM or for a punch biopsy (usual care). When a BCC is diagnosed, surgical excision will follow and a follow-up visit will be planned 3 months later. Several questionnaires will be filled in (EQ-5D, EQ-5D VAS, iMTA PCQ, and TSQM-9). We will perform statistical analysis, cost-effectiveness, and patient outcome analysis after data collection. **RESULTS:** This research started in January 2016 and is ethically approved. We expect to finish this study at the end of 2018. **CONCLUSIONS:** In this study, we will investigate whether RCM is at least as good in identifying BCC subtypes as conventional pathological investigation of skin biopsies. Anticipating that RCM is found to be a cost-effective alternative, it saves on direct medical consumption like labor of the pathologist and other medical personnel as well as materials related to treatment failure with at least equal effectiveness. **TRIAL REGISTRATION:** Clinicaltrials.gov NCT02623101; <https://clinicaltrials.gov/ct2/show/NCT02623101> (Archived by WebCite at <http://www.webcitation.org/6id54WQa2>). **KEYWORDS:** basal cell carcinoma; cost effectiveness; diagnosis; reflectance confocal microscopy PMID:27363577 PMID:PMC4945846 DOI:10.2196/resprot.5757