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


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 PMCID:PMC4945846 DOI:10.2196/resprot.5757