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Evaluating the Diagnostic Accuracy of Reflectance Confocal Microscopy to Diagnose Skin Cancer: Protocol for a Prospective, Multicenter Study.

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ABSTRACT

BACKGROUND:In the United Kingdom, 350,000 patients per year are referred to hospital clinics with suspicious moles, and approximately half undergo a biopsy to identify the 5%-10% who require further treatment. If cancer cannot be ruled out clinically and on the basis of biopsy results, the lesion is surgically removed. One type of precancerous mole, called lentigo maligna, is particularly challenging to delineate and treat. Reflectance confocal microscopy (VivaScope, Caliber Imaging & Diagnostics) is an imaging technique that can supplement dermoscopy in identifying whether a clinically suspicious mole is malignant and can better assess lentigo maligna margins for excision. It allows clinicians to visualize the skin lesion to a depth of 200 microns with subcellular resolution, described as quasi-histological, and therefore better guide more accurate diagnoses. **OBJECTIVE:**The aim of this paper is to describe a prospective, single blinded, multicenter study to examine patients with clinically suspicious moles or lentigo maligna to determine whether confocal microscopy can both reduce the number of unnecessary biopsies of moles and more accurately guide the surgical excision margins of lentigo maligna. **METHODS:**This study will prospectively recruit adults into the following two cohorts: diagnostic accuracy and margin delineation. The diagnostic accuracy cohort will assess people with clinically suspicious lesions suspected of being diagnosed with melanoma and having an equivocal finding on dermoscopy or persistent clinical suspicion despite normal dermoscopy. Diagnostic accuracy will include the sensitivity and specificity of VivaScope in comparison with the histological diagnosis as the gold standard for patients. The margin delineation cohort will assess the ability of VivaScope to accurately delineate the margins of lentigo maligna compared with that of dermoscopy alone using margins taken during Mohs micrographic surgery as the gold standard. The primary study outcomes will be the diagnostic accuracy of VivaScope for the first cohort of patients and margin agreement between VivaScope and the final pathology report for the second cohort of patients. **RESULTS:**Funding for this proposed research is being secured. **CONCLUSIONS:**The outcomes of the proposed study will indicate how many biopsies of nonmelanoma lesions, which are potentially unnecessary, could be prevented. This would reduce patient anxiety and cost to the National Health Service (NHS) in the United Kingdom. Improved margin delineation of lentigo maligna could also improve the surgical clearance rates and decrease overall cost. The results would demonstrate whether the adoption of VivaScope would potentially benefit patients and the NHS. **REGISTERED REPORT IDENTIFIER:**RR1-10.2196/9296. ©Naomi D. Herz, Anastasia Chalkidou, Fiona Reid, Stephen F. Keevil, Andrew Coleman, Emma Craythorne, Rakesh Patalay. Originally published in *JMIR Research Protocols* (<http://www.researchprotocols.org>), 09.08.2018. **KEYWORDS:**biopsy; dermoscopy; lentigo maligna; melanoma; reflectance confocal microscopy
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