Nevus doctor - Clinical decision support for primary care physicians

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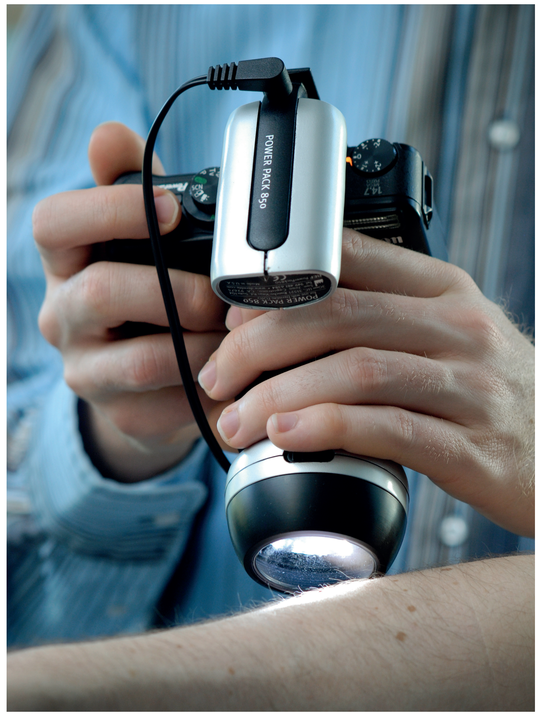
Background

Early diagnosis of skin cancer is challenging, especially in primary health care. Attempts have been made to program computers to help diagnose skin cancer. Computer-based analysis is commonly based on digital dermatoscopic images of skin lesions. Although such computer programs are commercially available, there is little research regarding the various steps in the clinical decision making process with such devices. The clinical decision support system Nevus doctor has been developed at the Norwegian Centre for E-health Research (formerly known as Norwegian Centre for Telemedicine) in collaboration with the University of Tromsø. The aim of the program is to help general practitioners (GPs) identify those skin lesions that need further attention, either through biopsy or by referral to a dermatologist.



The system is comprised of the following components:

1. An interactive online guide to help doctors select the clinically most suspicious lesions.
2. A computer program to analyse dermatoscopic images.
3. A scoring algorithm to assess the findings.

As only the computer program (component 2) has been tested previously, we now wish to assess the complete system in a clinical trial.

Methods

GPs examine patients who have given their consent to enroll in the study. In the intervention group the computer-based clinical decision support tool “Nevus doctor” in a first step assists doctors in the process of selecting skin lesions that are suggestive of cancer. In the next step a given skin lesion is photographed using a dermatoscope attached to the lens of the camera. The dermatoscopic image is then processed by the computer program “Nevus doctor” and a preliminary result is presented. Finally the GP reviews the result and assesses the clinical significance of the output by using guidelines presented by “Nevus doctor”. In this process the dermatoscopic image is also assessed by the doctor using the three-point checklist. Doctors in the control group have no access to the tool.

The patient is subsequently referred to a dermatologist and a complete skin examination is performed. The assessment of the dermatologist serves as the gold standard. Patients are currently enrolling and the trial is scheduled to end in 2020.

Primary outcome

Skin lesions selected by the GP are classified into three classes:

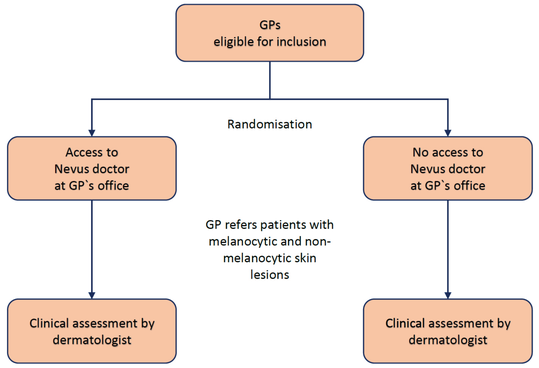
1. Not suspicious for skin cancer,
2. Somewhat suspicious for skin cancer,
3. Very suspicious for skin cancer.

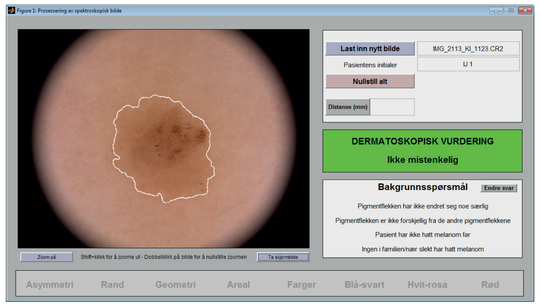
The reference standard is the specialist`s classification. The number of correct classifications are counted. Sensitivity and specificity scores are calculated.

Secondary outcomes

1. The number of skin lesions that were not selected by the GP but were later classified by the specialist to be suspicious for skin cancer.
2. The number of skin lesions biopsied or excised by the GP.
3. The GPs are asked to answer a questionnaire to assess the user experiences of operating the clinical decision support tool.

ClinicalTrials.gov identifier (NCT number): NCT03246412.





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