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One-stop-shop with confocal microscopy imaging versus standard care for surgical treatment of basal cell carcinoma: an open label, non-inferiority, randomized controlled multicenter trial.

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ABSTRACT

BACKGROUND: Routine punch biopsies are considered as the standard care to diagnose and subtype basal cell carcinoma (BCC) when clinically suspected. **OBJECTIVES:** We assessed the efficacy of a one-stop-shop concept using in vivo reflectance confocal microscopy imaging (RCM) as diagnostic tool versus standard care for surgical treatment in patients with clinically suspected BCC. **METHODS:** In this open-label, parallel-group, non-inferiority, randomized controlled multicenter trial we enrolled patients with clinically suspected BCC at two tertiary referral centers in Amsterdam, the Netherlands. Patients were randomly assigned to the RCM one-stop-shop (diagnosing and subtyping using RCM followed by direct surgical excision) or standard care (planned excision based upon the histological diagnosis and subtype of a punch biopsy). The primary outcome was the proportion of patients with tumour-free margins after surgical excision of BCC. **RESULTS:** Of the 95 included patients, 73 (77%) had a BCC histologically confirmed on surgical excision specimen. All (40/40, 100%) in the one-stop-shop group had tumor free margins. In the standard care group tumor free margins were found in all but two (31/33, 94%). The difference in the proportion of patients with tumor-free margins after BCC excision between the one-stop-shop group and the standard care group was -0.06 (90% confidence interval -0.17 to 0.01), establishing non-inferiority **CONCLUSIONS:** The proposed new treatment strategy seems suitable in facilitating early diagnosis and direct treatment for patients suffering from BCC, depending on factors such as availability of RCM, size and site of the lesion, patient preference and whether direct surgical excision is feasible. This article is protected by copyright. All rights reserved. **KEYWORDS:** Basal Cell Carcinoma; confocal microscopy; diagnostic services; operative surgical procedures; test-treatment pathway PMID:28391599 DOI:10.1111/bjd.15559