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Titel des Beitrags: Randomized controlled trial to evaluate the effects of ethyl-2-cyanoacrylate on pain intensity and quality of life in head and neck cancer patients suffering from cetuximab-induced rhagades during radioimmunotherapy: the support trial.

Abstract: Cetuximab is a chimeric monoclonal antibody against the epidermal growth factor receptor (EGFR). Skin reactions are the most common side effects of cetuximab. Rhagades of the tips of the fingers and toes, the heels and especially the interphalangeal joints are one of the most frightening and painful dermatological side effects that may develop from EGFR-inhibitor therapy. Rhagades are characterized by pain, severe tenderness and poor healing response. They are challenging to treat. Thus, rhagades often poses the most significant threat to the quality of life (QoL) for these patients. Ethyl-2-cyanoacrylate (ECA), an ethyl ester of the 2-cyano-2-propenoic acid, is often used as adhesive in a variety of different work settings in industry, i.e. as a component in nail-care products such as nail glue. In addition, ECA is used for various medical indications, such as for liquid bandages and for suture-less surgery. Wound healing can be accelerated with ECA. The purpose of the SUPPORT trial is to investigate the efficacy of ECA for the treatment of cetuximab-induced rhagades and to assess the clinical usefulness of the SUPO score, a new classification system for rhagades induced by EGFR-inhibitor therapy. The SUPPORT trial is an
open-label, prospective, randomized, national multicenter intervention study to evaluate the effectiveness of ECA versus the standard treatment of each institution on the pain intensity and QoL in patients with locally advanced head and neck cancer suffering from painful cetuximab-induced rhagades during radioimmunotherapy. Primary endpoint is the assessment of the pain intensity 24 hours after application of ECA or the standard treatment quantified by the visual analogue scale (VAS). Secondary endpoints are the evaluation of QoL assessed by the EORTC-QoL-C30 questionnaire and the Dermatological Life Quality Index (DLQI). During treatment with EGFR inhibitors it is necessary to recognize and manage side effects promptly to assure better patient QoL. The SUPPORT trial is the first randomized clinical trial evaluating a new treatment option for painful cetuximab-induced rhagades. Furthermore, the new SUPO score will be prospectively assessed in terms of clinical usefulness for classification of EGFR inhibitor-induced rhagades. Current Controlled Trials NCT01693159.