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Fauteck JD[1], Ackermann G, Birkel M, Breuer M, Moor AC, Ebeling A, Ortland C

Author information

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Actinic keratosis (AK) can be treated by photodynamic therapy (PDT), which is becoming a well-established tool in dermatology. Normally a precursor of the photosensitiser is applied topically and converted into protoporphyrin IX (PPIX) in the cells. By activating PPIX with light, the dysplastic cells will be destroyed. We report the results of two clinical studies investigating the properties of a novel self-adhesive 5-ALA-patch (PD P 506 A) intended for PDT of m to moderate AK on the face and head. The studies investigated the influence of patch application duration on PPIX-specific fluorescence and the pharmacokinetic properties of the 5-ALA patch. The PPIX fluorescence in AK lesions a normal skin after patch application (intraindividual comparison; application for 2, 3, 4, 5 h) was investigated in 13 patients using DYADERM Professional (Biocam). In the subsequent pharmacokinetic study 12 patients were treated with 8 patches each (4 h application). 5-ALA and PPIX were analysed in plasma (over 24 h) and urine (over 12 h). PPI specific fluorescence measured immediately after patch removal increased with increasing application duration to maximum at 4-h application. The fluorescence in AK lesions was more intense than in normal skin. A small increase of 5-ALA plasma concentrations was observed in 10 of 12 patients after applying 8 patches for 4 h, which rapidly declined to normal values after patch removal. The maximum increase was 3.7-fold of the pre-dose 5-ALA plasma concentration. No PPIX-concentrations above the lower limit of quantification were observed. PPIX-specific fluorescence in AK lesions can be steered by application duration of this novel 5-ALA patch. Application is safe and well tolerable. The observed small rise in 5-ALA plasma concentrations is regarded clinically irrelevant. Clinical efficacy of the patch in PDT will be investigated in further clinical trials.

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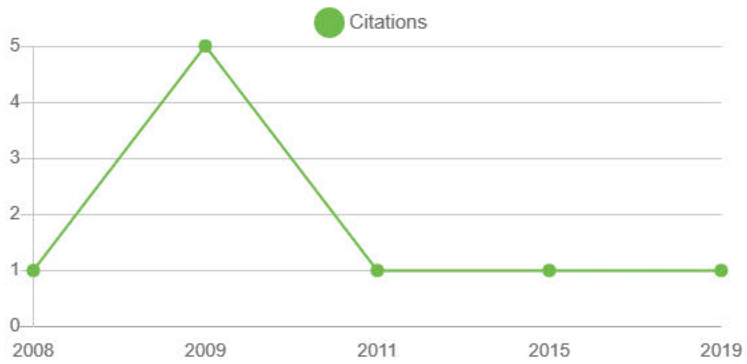

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