

**Abstract N°: 3717****Topical treatment of actinic cheilitis with Tirbanibulin: Results of a monocentric phase II study to investigate efficacy and tolerability**

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Introduction & Objectives:

Tirbanibulin 1% ointment is licensed for treatment of actinic keratoses. To date, there is no approved topical treatment for actinic cheilitis. There is an unmet need for topical therapy of actinic cheilitis.

Materials & Methods:

Twenty patients (10 female, 10 male, average age: 75.8 ± 6.8 years) with actinic cheilitis were treated with Tirbanibulin 1% on five consecutive days. Patients were examined after 7, 14 and 56 days. Efficacy was documented using optical coherence tomography (OCT). Additionally, the subject's self-assessment score, oral health DLQI and local skin reaction score (erythema, swelling, crusts, flaking, vesicles/pustules and erosion/ulceration) were analyzed to assess potential side effects.

Results:

All patients completed the study according to protocol. Twelve patients (60%) showed complete remission upon OCT and eight patients (40%) showed partial remission. In patients with partial remission, the size reduction of actinic cheilitis was >75% in two patients, 50 - 75% in five patients and <50% in one patient. On day 7, 10/20 (50%) patients showed a mild local skin reaction; 9/20 (45%) showed a moderate reaction and 1/20 (5%) a marked reaction. No severe or systemic adverse events were observed. The oral health DLQI improved significantly after treatment (6 vs. 3, $p=0.032$).

Conclusion:

These results suggest, that treatment of actinic cheilitis with Tirbanibulin appeared to be safe and effective.

