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Efficacy and safety of oral alitretinoin in severe oral lichen planus - results of a prospective pilot study.

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Abstract

BACKGROUND:

Patients with severe oral lichen planus refractory to standard topical treatment currently have limited options of therapy suitable for long-term use. Oral alitretinoin (9-cis retinoic acid) was never systematically investigated in clinical trials, although case reports suggest its possible efficacy.

OBJECTIVES:

To assess the efficacy and safety of oral alitretinoin taken at 30 mg once daily for up to 24 weeks in the treatment of severe oral lichen planus refractory to standard topical therapy.

METHODS:

We conducted a prospective open-label single arm pilot study to test the efficacy and safety of 30 mg oral alitretinoin once daily for up to 24 weeks in severe oral lichen planus. Ten patients were included in the study. Primary end point was reduction in signs and symptoms measured by the Escudier severity score. Secondary parameters included pain and quality of life scores. Safety parameters were assessed during a follow-up period of 5 weeks.

RESULTS:

A substantial response at the end of treatment, i.e. >50% reduction in disease severity measured by the Escudier severity score, was apparent in 40% of patients. Therapy was well tolerated. Adverse events were mild and included headache, mucocutaneous dryness, musculoskeletal pain, increased thyroid-stimulating hormone and dyslipidaemia.

CONCLUSIONS:

Alitretinoin given at 30 mg daily reduced disease severity of severe oral lichen planus in a substantial proportion of patients refractory to standard treatment, was well tolerated and may thus represent one therapeutic option for this special group of patients.