

A randomized, placebo-controlled, double-blind clinical trial of Curcuminoids in oral lichen planus.

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Lichen planus is a chronic immunological, mucocutaneous disease. In oral lichen planus (OLP) white lace like pattern, red atrophic changes and ulceration in oral mucosa can occur. The treatment for OLP is systemic and/or topical corticosteroids, however their effectiveness is limited by their side effects. Curcuminoids (Curcumin, demethoxy curcumin, bisdemethoxycurcumin) derived from *Curcuma longa* are known to have anti-inflammatory properties and are safe with few side effects even at high doses.

Objective:

To evaluate the efficacy and safety of Curcuminoids as an adjunct to short-course corticosteroids for the treatment of patients with OLP.

Study Design:

A phase II, randomized, double-blind, placebo-controlled trial with 100 eligible patients with OLP was planned. Patients were randomized into two groups: first group received 2000 mg of Curcuminoids per day and second group received placebo, for seven weeks. In addition both groups received 60 mg of prednisone per day for the first week. Primary outcome measure was change in

symptom scores from the baseline and secondary outcome measures were change in clinical sign from baseline and occurrence of adverse effect.

The parameters evaluated during the trial (i.e. at baseline and at the end of the study) included fasting glucose level and lipid profile (total cholesterol, LDL-C, HDL-C and Triglycerides) along with liver and kidney function tests.

Results:

- The first interim analysis did not show any significant difference in reduction of symptoms or signs between the placebo and the Curcuminoids group.
- Conditional power calculation suggested a less than 2 % chance that Curcuminoids group would have a significantly better outcome as compared with the placebo group, if the trial was continued to the completion. Therefore, the study was ended early for futility.
- Curcuminoids were well tolerated at the dose of 2000mg/day and there was no difference between side effects observed between Curcuminoids and placebo group.

Conclusion:

This first ever study of use of Curcuminoids in treatment of OLP, did not reach to any conclusion regarding their efficacy in the treatment of the disease. Hence it was ended early for futility. Though Curcumin was well tolerated at the dose level of 2000 mg/day in patients of OLP, the results suggested that future studies with a large sample size, multicenter design and a higher dose for longer duration should be considered. However, for the next step, an RCT of a shorter duration with higher dose of Curcuminoids and without an initial course of prednisone should be considered.