
**Preclinical and phase 1 clinical safety of Setarud (IMOD™), a novel immunomodulator**

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**ABSTRACT**

Background: A new herbal drug, Setarud (IMOD™) that has been shown to have beneficial immune effects was tested to determine its acute and chronic toxicity in animals and to establish its intravenous form maximum tolerated dose (MTD) in an open-labeled phase I clinical trial.

Methods: BALB/c and C57BL/6 mice and Wistar rats were monitored for general state and biochemical markers for chronic test. At the end of chronic test, animals examined macroscopically and histologically. HIV-infected asymptomatic male patients with CD4 counts more than 200, were enrolled in the trial. Baseline dose was calculated from the 10% lethal dose (LD10) established in laboratory animal studies. Dose escalation was performed in four cohorts of 3 patients receiving IMOD™ intravenously at a cohort-specific dose of 2, 4, 6.7, and 10 ml daily for 4 weeks. Patients were clinically examined at days of 1, 2, 3 and then weekly; and the safety was assessed on the basis of reports of adverse events, laboratory-test data and toxicity signs.

Results: LD50 values in acute toxicity test were 42-66 and 50-56 ml/kg in i.m. and i.p. injections, respectively. Total scores of embryotoxicity during pregnancy were significantly lower in the Setarud group ($p < 0.05$). Pre-implantational deaths in the Setarud group were significantly higher, but post-implantational deaths level was lower than those in the control group. Inhibition of ossification in the skeletons of the fetuses and incidence of still birth were significantly higher while body weight of new-born rats of treatment group in the first month of their lifes were lower than those of the control group. In all four cohorts, there were no major side effects or dose-limiting toxicity, except for a mild sweating and weight loss in two patients from the first group that was reversed without discontinuation of the treatment. No clinically relevant trends in laboratory test results or ECG changes were noted. No adverse effect due to IMOD™ was observed at one month of follow-up. Maximum tolerated dose of IMOD™ was 10 ml a day.

Conclusion: Results of this study has identified a safe dose of IMOD™ that can be used in future clinical trials.

**KEYWORDS**

Setarud, IMOD™, Acute toxicity, Chronic toxicity, Maximum Tolerated Dose

**FULL TEXT:**

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Refbacks

- There are currently no refbacks.
Basic research. Efficacy of Setarud (IMOD. TM.), a novel electromagnetically-treated multi-herbal compound, in mouse immunogenic type-1 diabetes. Seyed Sajad Mohseni-Salehi-Monfarejad. 1,2. In the present study the effect of IMODTM as a novel natural immunomodulator with very impressive antioxidative properties has been tested in MLD STZ-induced mouse type 1 immunogenic diabetes. Materials and methods. Animals and Reagents.