

# Safety and efficacy of lentinan nasal drops in patients infected with the variant of COVID-19: a single-center, randomized, placebo-controlled trial

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July 24, 2023

## Abstract

**Objective:** Lentinan has antiviral, anti-tumor, immunomodulatory, stimulating interferon production, and other pharmacological effects. Previous animal experiments have shown that lentinan nasal drops can assist(Corona Virus Disease 2019,COVID-19) vaccine to induce high levels of neutralizing antibodies and can effectively resist the invasion of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This study aimed to evaluate the safety and efficacy of lentinan nasal drops in patients infected with COVID-19 through a dose-escalation study and a placebo-controlled trial. **Methods:** The study was divided into two phases: Phase I: a dose escalation trial in which 24 COVID-19 patients were enrolled, that is, 12 in the escalation dose group (50, 75, and 100 µg/day) and 12 in the standard treatment group. The aim was to evaluate the safety and tolerance of lentinan nasal drops. The second stage was a placebo-controlled study. The optimal dose group of the first stage was used as the therapeutic dose, and the sample size was expanded to verify the anti-COVID-19 efficacy of lentinan nasal drops. **Results:** In the dose-increasing study, lentinan nasal drops showed good safety, and no serious adverse reactions occurred. The virus shedding time of the 100 µg dose group was significantly shorter than that in the control group (7.75±1.71 VS 13.41±3.8 d) (p=0.01), and the 100 µg/day lentinan nasal drops were tolerated well. The results of the placebo-controlled study showed that compared with that in the placebo group, the time for COVID-19 antigen to turn negative was significantly shorter in the 100 µg lentinan nasal drop group (p=0.0298), but no significant difference was observed in symptom improvement between the two groups. In the placebo-controlled study, two patients experienced mild nasal discomfort with nasal drops, but the symptoms relieved themselves. **Conclusion:** Lentinan nasal drops are tolerated well and can shorten the time of virus clearance.

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