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# Interferon-gamma in the prevention of severe burn-related infections: a European phase III multicenter trial. The Severe Burns Study Group

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PMID: 9504568 DOI: [10.1097/00003246-199803000-00010](#)

## Abstract

**Objectives:** To determine the efficacy and tolerance of interferon-gamma-1b (IFN-gamma) for the prevention of death related to infection in patients with burn injury who were at risk for infection. The positive anti-infective effects of IFN-gamma observed in animal models and in clinical studies provided the rationale for this study.

**Design:** Randomized, double-blind, placebo-controlled, phase III multicenter trial, with a group sequential design, conducted at 23 European burn centers.

**Patients:** Two hundred sixteen patients with major critical burn (Abbreviated Burn Severity Index score of > or = 7).

**Intervention:** Patients were randomized to receive IFN-gamma (100 microg) or placebo daily by subcutaneous injection for up to 90 days.

**Measurement and main results:** The primary end point (the incidence of death related to infection within 90 days from the start of treatment) was similar in the two treatment groups. There were no significant differences between the two treatments in any of the secondary end points (all causes of mortality at 90 days, incidence of infectious complications, duration of intensive care unit or hospital stay, and scar formation at 90 days).

**Conclusion:** IFN-gamma did not protect burn patients from infections or decrease the mortality from infections.

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