

Oral presentation

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## Immune-based therapy using gamma interferon ingaron in the treatment of HIV/AIDS patients with active pulmonary tuberculosis (PTB) not previously highly active antiretroviral therapy (HAART)

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### Background

Interferon gamma is a licensed product for treating certain immune deficiency diseases, but its use in people with HIV is experimental. IFN- is normally made by CD4 T-cells – the cells which are depleted in people with AIDS and it has antineoplastic effects and antiviral activity mediated by immunomodulatory effects. At a cellular level these include macrophage activation, stimulation of antigen presentation through class I and class II major histocompatibility complex molecules, regulation of leukocyte-endothelium interaction, and effects on cell proliferation and apoptosis. It is therefore theorized that giving HIV-positive people co-infected with TB supplementary injections of interferon gamma may help boost their immune response.

### Objective

To obtain preliminary information on the safety, immunologic and virologic effects of IFN-gamma in adults co-infected with HIV and TB with immune reserve (CD4T-cell count above 350 cells/ml) on TB medication but not on antiretroviral therapy.

### Materials and methods

51 HIV-infected persons newly diagnosed with active PTB were recruited in the special HIV and TB unit of the second city tuberculosis hospital in Saint Petersburg, Russia into an observational, prospective study between March and

December 2005. All the patients had a median CD4 cell count of above 350 cells/ml and were not previously on HAART. 21 patients (41.2%), apart from standard TB medication also received interferon gamma( $\gamma$ -IFN) injection (Ingaron) at a dose of 500 000 i.u. subcutaneously three times weekly for eight weeks, while the rest 30 (48.8%) received similar TB treatment plus placebo. They were assessed clinically weekly, while laboratory investigations were conducted at the initiation of therapy and at weeks 4 and 8.

### Results

Interim assessment of the outcome of TB treatment at 8 weeks of follow up showed a remarkable improvement of clinical conditions and immunologic responses of the patients receiving gamma interferon (Ingaron) as against those in the control group. In general,  $\gamma$ -IFN therapy was well tolerated. The major adverse event thought to be possibly  $\gamma$ -IFN associated was low grade fever. Increase in CD4+ lymphocyte counts and decrease in plasma HIV RNA concentrations were observed in the study group. CD4+ increased from  $656.2 \pm 41.3$  to  $728.4 \pm 74.7$  cells/ml ( $p > 0.05$ ) (table 1) while plasma RNA became undetectable in 11 patients in the study group as against nil in the control group.

## Conclusion

Gamma interferon therapy in patients co-infected with HIV and tuberculosis receiving TB medications is safe, improves clinical outcome and enhances host defense mechanism. Larger studies will be needed to assess the drug's long term clinical efficacy in the treatment of HIV-associated complications such as PTB.

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