CIGB CENTRO DE INGENIERÍA GENÉTICA Y BIOTECNOLOGÍA

CORONAVIRUS

Cuba

#TrabajamosPorSuSalud

Nasalferon

Recombinant interferon alfa-2b in nasal drops

Biomedical Project

CIGB

ABSENCE OF INTERFERON IN LUNGS FROM FATAL CASES OF INFLUENZA

BY

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Condition that has also been described in patients with COVID-19

> Science. 1972 Jun 23;176(4041):1326-7. doi: 10.1126/science.176.4041.1326.

Interferon administered orally: protection of neonatal mice from lethal virus challenge

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1st report on IFN orally

Abstract

Interferon was identified in the milk of mice injected with an interferon inducer. The kinetics of interferon appearance in serum and in milk were similar, but maximum concentrations in milk were 10 to 20 percent of those in serum. Interferon administered orally to neonatal mice was detected in their serums. Significantly more newborns survived an oral challenge with vesicular stomatitis virus when interferon had been induced in the lactating mothers.

Reported history of use of IFN alpha in respiratory virus infections

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Prophylactic and antiviral effect demonstrated in infections

INDUCED AND ACQUIRED

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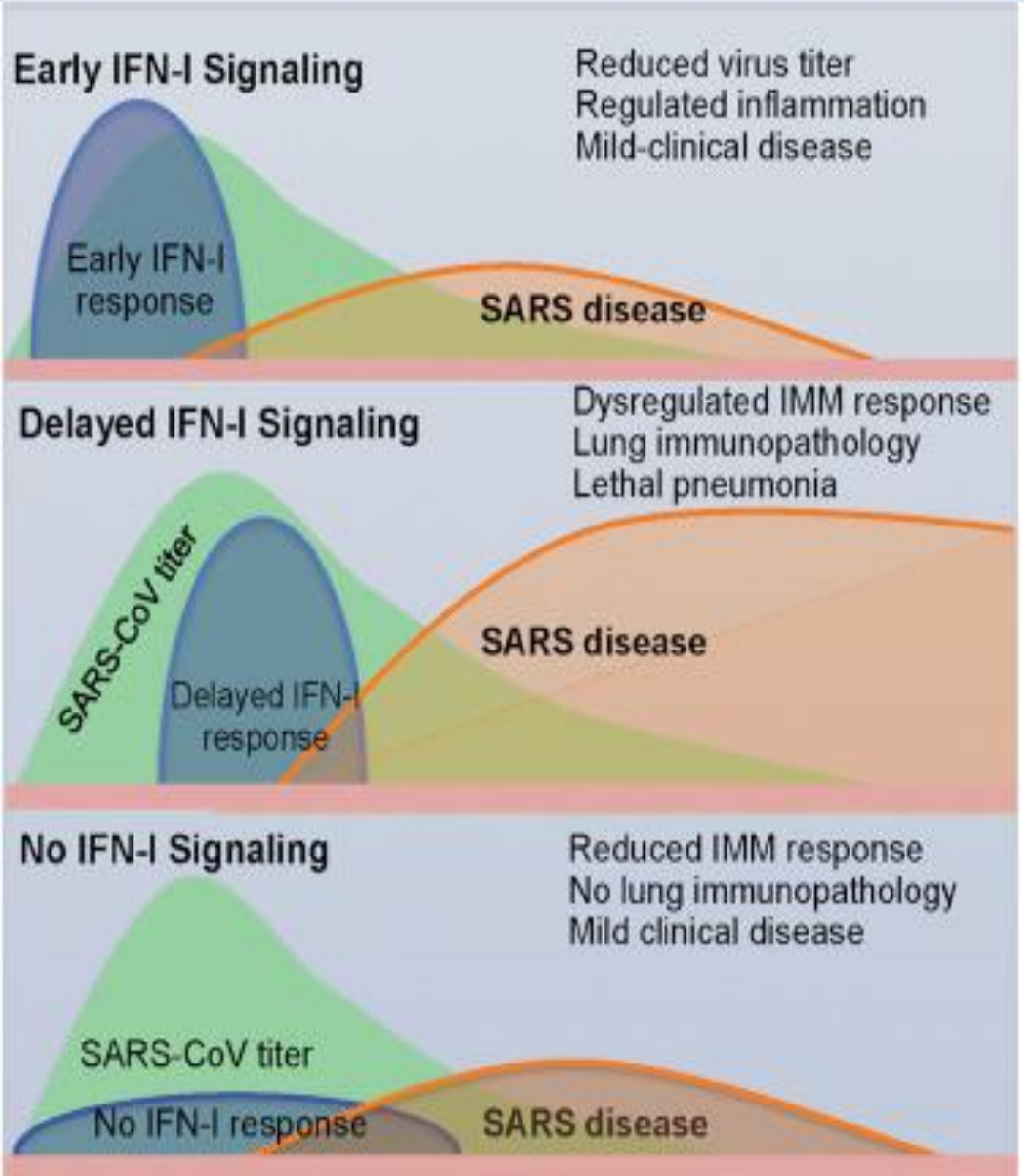
Background of the use of IFN type I as treatment of coronavirus.

VERY EFFICIENT in use from prophylaxis

INEFFICIENT and with adverse events in aggravated patients.

EFFICIENT in newly started infection



Advantages of type I IFN administered by nasal drops.

1. Deliver the drug directly to the entry area of the virus causing the disease.
2. The oral-naso-pharyngeal cavity and the entire gastrointestinal tract is rich in high concentrations of specific receptors for type I IFN.
3. Orally administered IFN is retained by the proximal tissue of the lymphoid region, including the posterior nasal cavity.

Advantages of type I IFN administered by nasal drops.

4. From LOW doses, HIGH results are achieved.
5. Independent effect of serum IFN levels.
6. Eliminates or significantly reduces toxicity.
7. Bioavailability studied and demonstrated from the front of the nose to the nasopharynx.

Nasalferon and prophylactic use for COVID-19

Route	Dose and schedule	Use
Nasal drops	1 drop (0,05 mL) in each nostril 2 times a day for 10 consecutive days. **Total daily dose 2 MUI** **1 drop Nasalferon = 0.5 MUI of IFN alpha**	Self application Conservation in refrigeration

Strength: 10 x 10^6 IU
Presentation: 2 mL solution

Nasalferon and prophylactic use for COVID-19

Maximum recommended dose: 1 drop in each nostril, 4 times a day (every 6 hours), representing 4 MUI of IFN alpha daily.

Absolute contraindication: individuals with hypersensitivity to interferon alfa or to any of the excipients in the preparation (TIOMERSAL)

Precautions: Pediatric population, pregnant women, patients with autoimmune diseases.

Overdose Hazard: NONE

Drug interaction: NONE

Conservation mode: from 2 to 8 degrees celsius.

Nasalferon and prophylactic use for COVID-19

Population	N	Infected	Protection
Health personnel	**3741**	**48** (1,3%)	**98,7%**
Vulnerable individuals (age ≥ 85, co-mobidities)	**82**	**0**	**100%**
Healthy people in indirect exposure to the virus	**1400**	**0**	**100%**
Total	**5223**	**48** (0,9%)	**99.1%**

Unpublished data.
Source: Active pharmacovigilance in sentinel centers.
Cuban Ministry of Public Health

Title Page

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Title: An experimental trial of recombinant human interferon alpha nasal drops to prevent coronavirus disease 2019 in medical staff in an epidemic area

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was observed between January 21 to February 23, 2020. There were no serious adverse effects in the 2944 subjects treated during the intervention period.

Conclusion In this investigator-initiated open-label study, we observed that rhIFN-α nasal drops can effectively prevent COVID-19 in treated medical personnel. Our results also indicate that rhIFN-α nasal drops have potential promise for protecting susceptible healthy people during the coronavirus pandemic.


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