

4th International Conference and Exhibition on

Lung & Respiratory Care

August 01-02, 2016 Manchester, UK

Efficacy and safety of iota-carrageenan nasal spray versus placebo in early treatment of the common cold in adults: The ICICC trial

Stephan Koelsch

Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Iota-carrageenan (I-C) is active against respiratory viruses in vitro and was effective as nasal spray in three clinical trials with common cold patients. To further investigate I-C, a fourth randomized, placebo-controlled, double-blind clinical trial was conducted in 200 adult patients with self-diagnosed colds that were confirmed by baseline symptom scores. Respiratory viruses were quantified at baseline and on treatment day 3 or 4. Primary endpoint was the mean total symptom score of 8 cold symptoms on Days 2 to 4. The primary endpoint did not demonstrate a statistically significant difference between I-C and placebo but showed a trend towards I-C benefit. Exploratory analyses indicated significant reduction of cold symptoms in the I-C group and also substantiated I-C's activity against rhinovirus. To observe trends rather than statistically significant outcomes obviously was based on an unexpected low power of the trial. In particular, the proportion of virus-positive patients was smaller than anticipated. Only 23.6% had rhinovirus in contrast to 50-90% in other studies. This low frequency of rhinovirus-positive patients in the ICICC study demonstrates that there may often be a trade-off when the standard design for cold studies is used. When a controlled study tries to recruit patients at the earliest stages of a cold, patients may incorrectly believe they are coming down with a cold, prior to full blown cold symptoms. Hence, the peculiarities of the ICICC study may trigger a discussion among the scientific community about more suitable study designs to investigate common cold treatments.

Biography

Stephan Koelsch studied Biology at the University of Mainz until 1994. He then started his PhD studies in Immunology and completed in December 1998. As a Global Senior Medical Advisor at Boehringer Ingelheim, he is responsible for the Consumer Health Care (CHC) Medicine Cough & Cold area. He is author/co-author of more than 20 papers in reputed journals.

stephan.koelsch@boehringer-ingelheim.com

Notes: