Preventing Airborne Infection With an Intranasal Cellulose Powder Formulation (Nasaleze Travel®)

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ABSTRACT

A total of 52 volunteers were recruited to take part in a dual-centered, randomized, blinded study so investigators could determine whether the level of airborne infection could be significantly reduced in patients randomly assigned to treatment with either Nasaleze® cellulose extract alone or a combination of Nasaleze cellulose and powdered garlic extract (PGE). One puff into each nostril was recommended, and volunteers who developed an infection while traveling were told to use at least 3 puffs per nostril until symptoms were reduced. This study took place over an 8-wk period across Finland and the United Kingdom between November 2006 and March 2007. Volunteers were instructed to use a 5-point scale to assess their health and to record infectious episodes and symptoms in a daily diary. The active-treatment group (Nasaleze cellulose with PGE) experienced significantly fewer infections than the control group (20 vs 57; $P<.001$) and far fewer days on which an infection was obviously present (126 d in the active group vs 240 d in the control group; $P<.05$). Consequently, volunteers in the active group were less likely to pick up an airborne infection when PGE was added to this novel cellulose extract. Volunteers in the control group were much more likely to report more than 1 infectious episode over the treatment period or to endure longer periods of infection. The investigators concluded that the combination Nasaleze Travel formulation significantly reduced the number of airborne infections to which volunteers were exposed while traveling.

Keywords: Nasaleze cellulose extract; powdered garlic extract

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INTRODUCTION

The common cold is the world's most widespread viral infection; most adults develop approximately 2 to 5 colds per year, irrespective of where they live. More than 200 different viruses are known to cause symptoms of the common cold. Some, such as rhinoviruses, seldom produce serious illness. Others, such as parainfluenza and respiratory syncytial virus, generally produce mild infection in adults but can precipitate severe lower respiratory tract infection in young children.

Rhinoviruses (from the Greek *rhin*, meaning "nose") cause an estimated 30% to 35% of all adult cold infections and are most active in early fall, spring, and summer. More than 110 distinct rhinovirus types have been identified. These agents grow best at temperatures of about 91°F—the temperature inside the human nose. Scientists believe that coronaviruses cause a large percentage of all adult colds. These viruses bring on colds primarily in the winter and early spring. Of the more than 30 types of coronaviruses that have been identified, 3 or 4 are known to infect humans. The importance of coronaviruses as a cause of colds is difficult to assess because, in contrast to rhinoviruses, they are difficult to grow in the laboratory.

Approximately 10% to 15% of adult cold infections are caused by viruses that are also responsible for other, more severe illnesses; these include adenoviruses, coxsackie viruses, echoviruses, orthomyxoviruses (including influenza A and B viruses, which cause flu), paramyxoviruses (including several parainfluenza viruses), respiratory syncytial virus, and enteroviruses.

The causes of 30% to 50% of adult colds that are presumed to be viral in origin remain unidentified. The same viruses that produce colds in adults appear to cause colds in children. The relative importance of various viruses in pediatric colds, however, is unclear because it is difficult to isolate the precise cause of symptoms in studies of children with colds.

In cases of airborne infection, the initial entry point in a human being is the nasal cavity. Touching the skin or environmental surfaces, such as telephones and stair rails, that have cold germs on them and then touching the eyes or nose and inhaling drops of mucus full of cold germs from the air are the most common methods of transmission.

Unfortunately, airborne infections are commonplace all year round nowadays; although the chance of picking up an infection in the summer months is only 1 in 4 compared with the chance in winter, special factors may increase this risk. Long-haul jet flights appear to pose a particular risk in that at no other time are humans likely to be squeezed as tightly together with 400 potential sources of common cold infection. The chances are that any number of passengers will have the tendency to spread an airborne infection in the confined space of a jetliner, making this an ideal environment for transmission of airborne disease. Experiments on exposing uninfected volunteers to others with common cold infections have shown that the chances of catching a cold are directly related to the number of hours of exposure to infection. Hence, one is much more likely to get a cold on a long-haul flight to the United States than on a short hop to Europe. Current lifestyles often demand air conditioning, which may contribute to infection. Although the lining of the nose is covered by a thin layer of mucus that protects against infection, air conditioners unfortunately extract moisture from the air; therefore, they may cause some drying of the protective mucous blanket in the nose and predispose to infection. This feature is one that

the active test compound Nasaleze Travel® (cellulose and powdered garlic extract [PGE] combination; Nasaleze Limited, Isle of Man, United Kingdom) may improve significantly, simply because of the way it works. Cold air may also help viruses establish a hold in the nose because they reproduce better in a cold environment.

Traveling by public transportation can significantly increase the risk of viral infection. Although individuals may have already been exposed to current common cold viruses at home, they are likely to encounter new viruses to which they have no immunity as they circulate in public. Travelers could actually be responsible for introducing new viruses into a foreign country if they have an active infection when they arrive for a holiday or a business meeting. With modern jet travel, viruses are spread rapidly, which is why influenza spreads so quickly around the world during an epidemic.

Unfortunately, because of the extensive number of airborne infections, reinfection is common. Published literature on the activity of garlic extracts (among others) against viral infection is sparse.[1,2] It has been reported, however, that during an influenza epidemic, the former Soviet Union imported more than 500 tons of garlic cloves for acute treatment.[3] Among the viruses thought to be sensitive to garlic extracts are human cytomegalovirus, human rhinovirus type 2, herpes simplex types 1 and 2, and influenza B. Many consumers already take natural remedies such as *Echinacea*, vitamin C, zinc, and garlic supplements for preventive purposes and report an absence of infection with colds and symptoms associated with viral replication.[4]

Cellulose powder is used as a thickener in many liquid nasal sprays and is generally regarded as safe for consumption. The unique proprietary grade of micronized cellulose used in this study (Nasaleze®) is administered with a patented device that ensures that a suitable amount of material will be drawn from the container and delivered into the nose. Compared with liquid nasal sprays, which require preservatives, powdered cellulose inhibits bacterial and viral growth to a limited extent. Although it is not a medicine, this formulation is classified as a medical device that is safe to use throughout the year. This powdered cellulose product addresses the cause of allergic reactions, rather than the symptoms, because it works as a facial mask in preventing inhaled pollen, dirt, and allergens from reaching the lungs. In a healthy individual, the nose and the nasal tract positively extract these materials from inhaled air as it passes through on its way to serve the lungs. This filtration effect is created by very low peripheral air pressure (generated by the internal shape of the nasal tract) as the air goes through the system. This linear, low air pressure area positively attracts entrained allergens and at the same time attaches this material onto the mucous membranes (Figs 1 and 2).[5]

Mucus has the ability to rapidly adsorb and render harmless any particle that touches its surface. Spent mucus is eventually disposed of via the digestive tract. Thus, clean, allergen-free air is supplied to the lungs. A unique feature of the cellulose powder formulation described herein is that it turns into a gel on contact with the moisture that is always present in the nasal cavity. This gel is similar to normal mucus and helps to maintain delivery of a supply of clean air to the lungs.

This survey was designed to determine whether the addition of a simple PGE to Nasaleze powdered cellulose would enhance the capability of this formulation to trap airborne infections, disarm them, and remove them safely into the stomach during normal mucociliary clearance. A randomized, blinded study design was applied

in 2 countries—Finland and the United Kingdom—to test whether the addition of PGE would increase the potential for preventing airborne infection among individuals traveling locally and nationally during the winter, when airborne infections are at their peak.

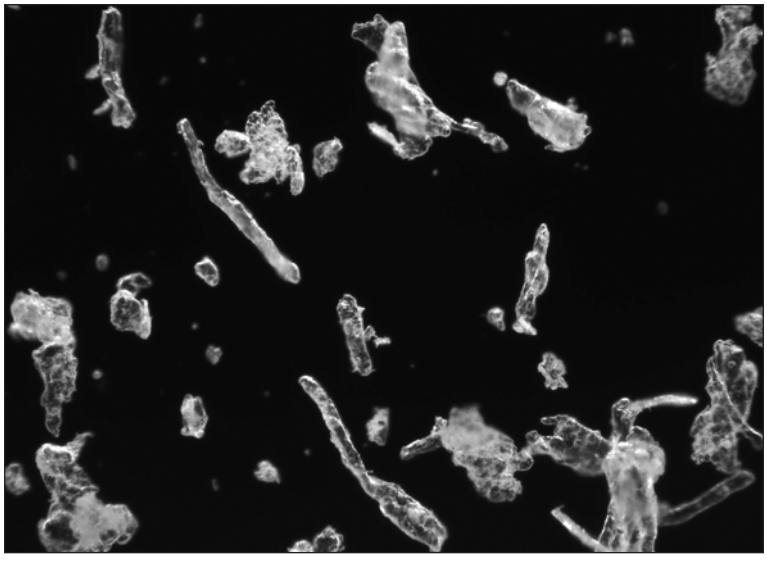

Fig 1. Combination cellulose powder extract and PGE (Nasaleze Travel) before instillation into the nasal tract.

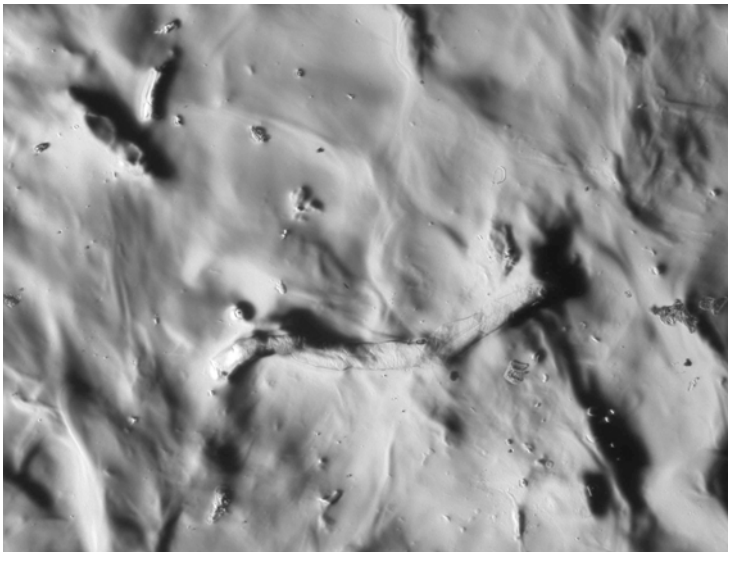

Fig 2. Combination cellulose powder extract and PGE (Nasaleze Travel) after instillation into the nasal tract.[5]

From Emberlin JC, Lewis RA. *Curr Med Res Opin.* 2006;22:275-285.[5]

METHODS

After completion of recruitment through advertisements in daily newspapers in London and Helsinki, 52 participants were selected. All volunteers kept a diary of their general well-being for 8 wk on a 5-point scale as they traveled to and from work or completed various other trips across the United Kingdom or Finland (and, in some cases, internationally) (Table 1).

Table 1. Self-Assessment Scale for Recording General Well-Being During the Study Period

5 = well, no problems
4 = quite well with occasional sneeze, not disruptive to normal routine
3 = can feel a cold coming on, some minor symptoms
2 = feeling low and beginning to exhibit symptoms
1 = full cold symptoms (headache, sneezing, runny nose, tiredness)

If an infection occurred, volunteers noted the number and variety of symptoms, the day recovery began, and the day they felt completely better. The volunteers were separated into 2 groups of 26 participants each and were matched for age. The average age in each group was 38 y, and all participants were actively employed. Volunteers who were already taking a garlic supplement were excluded, as were those who reported that they were housebound. A simple random number generator assigned volunteers to the active or the control group, and all were instructed to take 1 sniff in each nostril every day, according to the manufacturer's recommendation; if an infection developed, participants were instructed to take up to 3 sniffs per nostril on each day that the infection was present, so it could be determined whether the infectious period was reduced in either group. Randomization codes were kept secure at the Herbal Research Centre and were not broken until all diaries had been returned. Volunteers were contacted several times during the study period to ensure that they were complying with the dosage regimen and that diary entries were made daily. Participants in Finland were also encouraged to record their daily diary scores online using a secure Web site.

Diary Analysis

After the diaries had been returned, the number of infections experienced by volunteers was counted. Active infection was defined as a score of 3 or less that lasted for 4 days in succession. The duration of symptoms was expressed as the number of days on which a score of 3, 2, or 1 was recorded; average recovery time ended with a score of 4 or 5 taken across all recorded infections. The number of volunteers in each group who did not experience a single airborne infection throughout the study period was recorded.

Statistical Analysis

The total number of infectious episodes, the average length of symptoms in days, and the number of days on which the subject was challenged by an active infection were subjected to calculations of standard deviation, sample variance, and standard error of the difference of the means. Data were analyzed by means of Student *t* test, so that a probability coefficient could be attained that would allow for the calculated number of degrees of freedom.

RESULTS

No participants withdrew from the study; therefore, an intention-to-treat analysis was performed on all completed diaries. At the end of the 56-day study, 57 major infections had been recorded in the control group, but the active group had recorded a total of only 20 infections. This result is highly significant ($P<.001$) in favor of the addition of PGE to Nasaleze cellulose powder as a preventive agent for airborne infections acquired during travel (Table 2).

Table 2. Results of Randomized Blinded Comparison Between 2 Types of Nasaleze Cellulose Extract, One Combined With PGE, Administered Intranasally

Subpopulation	Control Group (Nasaleze—cellulose extract alone)	Active Group (Nasaleze Travel—cellulose extract combined with PGE)	*P* Value
Active infections during the study period	57	20	<.001
Volunteers with no infection	6	10	NS
Volunteers with a serious infection lasting longer than 7 days	12	6	NS
Days reported with an active infection	240	126	<.05
Volunteers who experienced multiple infections during the study period	11	2	<.05

The control group reported 12 serious cases in which infection lasted for 7 days; the active group reported only 6 such cases. Similarly, the number of days on which active infection was present, warranting a recorded score of 3 or less, was 240 in the control group; in the active group, this value was 126 days. This result is also highly significant ($P<.05$).

During this study, 11 volunteers who were taking the control compound experienced multiple infectious episodes; only 2 volunteers who were taking active treatment had this experience, which suggests that this was indeed a preventive option ($P<.05$ level of significance).

Details of the statistical analysis indicate that the sample variance and the standard deviation were low, and that although most members of the 2 groups were female volunteers, they were well matched statistically with a standard error for the difference of the means of just 0.76 for the number of active airborne infections reported by each group, so that probability with a Student t test was $P<.01$. Significance dropped to $P<.05$ for the number of volunteers with multiple infectious episodes and the total number of reported days with an active infection. Those with a serious infection that lasted 7 days and the number of participants who did not report an infection at all did not reach significance, but clear differences between groups were noted. The investigators believed that the Nasaleze Travel combination treatment product proved superior to the Nasaleze cellulose extract treatment alone.

Volunteers were also asked to record in their diaries any other concerns that they had during the study, such as comments about the acceptability of taking the product, adverse effects, tastes, or other reasons that might warrant discontinuation of treatment. Generally, the product was extremely well tolerated in both groups, although in the active group, several volunteers (n=3) wrote that they could easily taste the PGE; however, this did not stop them from completing treatment.

DISCUSSION

In this pilot investigation, 2 inert cellulose powder formulations, both dosed intranasally through a novel, patented delivery system, were compared in a randomized, blinded study, so the investigators could determine which formulation provided the best protection against various airborne infections. The volunteers were encouraged to go about their normal daily lives while traveling within local and national boundaries. Some volunteers even ventured out internationally, so this was a genuinely fair assessment of the relative dangers of picking up an airborne infection during the winter, and of assessing how this might be prevented.

The results clearly favored the Nasaleze Travel combination formulation. They indicate that a significant reduction in the number of airborne infectious pathogens picked up by volunteers was seen in this group as opposed to outcomes in the Nasaleze cellulose powder alone group.

Examination of volunteer diaries clearly showed that the control group suffered much more than the active group in terms of the number and duration of infectious episodes. Thus, it is concluded that the addition of a potentially antiviral compound, in this case, a PGE, can significantly reduce the number of infectious challenges that people meet when they travel. The results also suggest that infection and reinfection may be effectively prevented through its daily use throughout the year, with reduced sick days leading to an enormous potential savings to national economies. This product clearly exhibits excellent antiviral activity, confirming that Nasaleze cellulose extract combined with PGE is an excellent carrier that allows any number of agents to be spread throughout the nasal cavity for an extended period of time. This novel property clearly warrants further investigation to determine the nature and method of its viral destruction when administered intranasally.

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