Preventing Air-Borne Infections with an Intranasal Cellulose Powder Formulation

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ABSTRACT

Fifty two volunteers were recruited to take part in a dual centred, randomized, blinded study to determine whether the level of airborne infections could be significantly reduced in patients receiving either plain Nasaleze cellulose extract or a combination of Nasaleze cellulose with PGE added (powdered garlic extract).

Volunteers were randomized to receive a plain cellulose extract delivered intra nasally or the same cellulose formulation with added PGE (powdered garlic extract). One puff into each nostril was recommended and if the volunteer caught an infection whilst travelling then at least 3 puffs per nostril were recommended until the symptoms reduced. The study took place over an 8 week period across Finland and England between November and March 2006/07. Volunteers were instructed to use a five-point scale to assess their health and record any common cold infections and symptoms in a daily diary. The active-treatment group (Nasaleze with PGE) had significantly fewer colds than the control group (20 vs 57, P<.001). The active treatment group also experienced far fewer days where a viral infection was obviously present (126 days in the active group vs 240 days in the control group p <0.05). Consequently, volunteers in the active group were less likely to pick up an airborne infection with the addition of PGE to this novel cellulose extract. Volunteers in the control were much more likely to get more than one cold over the treatment period or to suffer much longer periods of infection. This unique Nasaleze Cold formulation can significantly reduce the number of airborne infections that volunteers are exposed to whilst travelling throughout their respective countries.

Keywords: Nasaleze cellulose extract, Powdered garlic extract

INTRODUCTION

The common cold is the world's most widespread viral infection, with most people suffering approximately two to five colds per year. More than 200 different viruses are known to cause the symptoms of the common cold. Some, such as the rhinoviruses, seldom produce serious illnesses. Others, such as parainfluenza and respiratory syncytial virus, produce mild infections in adults but can precipitate severe lower respiratory infections in young children.

Rhinoviruses (from the Greek rhin, meaning "nose") cause an estimated 30 to 35 percent of all adult colds, 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 degrees Fahrenheit, the temperature inside the human nose.

Scientists think coronaviruses cause a large percentage of all adult colds. They bring on colds primarily in the winter and early spring. Of the more than 30 kinds, three or four infect humans. The importance of coronaviruses as a cause of colds is hard to assess because, unlike rhinoviruses, they are difficult to grow in the laboratory.

Approximately 10 to 15 percent of adult colds are caused by viruses also responsible for other, more severe illnesses: 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 percent of adult colds, presumed to be viral, 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's difficult to isolate the precise cause of symptoms in studies of children with colds.

This is primarily an airborne infection, whose primary entry point in a human being is the nasal cavity. Touching your skin or environmental surfaces, such as telephones and stair rails, that have cold germs on them and then touching your eyes or nose or 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 and although the chance of picking up an infection in the summer months is only 1 in 4 compared to winter there are some special factors that may increase the risk. Long haul jet flights appear to pose a special risk as there are no other periods when we are 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 temerity 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, you are much more likely to get a cold on a long haul

flight to the USA compared with a short hop to Europe. Our lifestyles often demand air conditioning which may contribute to infection. Although the lining of the nose is covered with a thin layer of mucus which protects against infection unfortunately air conditioners extract moisture from the air and therefore they may cause some drying of the protective mucous blanket in the nose and predispose to infection. This feature is one that our active test compound Nasaleze Cold® will significantly improve. The cold air may also help viruses to establish a hold in the nose as they reproduce better in a cold nose.

Travelling itself to different population areas, on public transport can significantly increase the risk of viral infection as we have probably already been exposed to all the current common cold viruses in our home environment but are likely to encounter quite new viruses, to which we have no immunity, as we circulate amongst our fellow human beings! We could ourselves be responsible for introducing new viruses into a foreign country if we arrive at a holiday or business destination with an active infection. With modern jet travel viruses are rapidly spread and this is why influenza spreads so rapidly around the world during an epidemic.

Sadly, since there are so many airborne infections available re-infection is prevalent.1 Published literature on the activity of garlic extracts (amongst others) against viral infections is sparse.2,3 but one report 4 describes that during an influenza epidemic, the former Soviet Union imported more than 500 tons of garlic cloves for acute treatment. Among the viruses thought to be sensitive to garlic extracts are the human cytomegalovirus, human rhinovirus type 2, herpes simplex types 1 and 2, and influenza B. Many consumers already take natural remedies including Echinacea, vitamin C, Zinc and garlic supplements as a preventive and report an absence of infection 5 colds or symptoms associated with viral replication.

Cellulose powder is used as a thickener in many liquid nasal sprays and is generally regarded as safe. The unique proprietary grade of micronized cellulose in this study (Nasaleze®) uses a patented device that ensures delivery into the nose of a suitable amount of material drawn from the container. Compared with liquid nasal sprays, which require preservatives, powdered cellulose inhibits bacterial and viral growth to a limited extent. While not a medicine, it 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. This mechanism was also thought to help protect an individual from attack by airborne pathogens in particular viruses. In a healthy individual, the nose and nasal tract extract these materials from the inhaled air, including air that has been exposed to mucus membranes and therefore been stripped of allergens. Mucus has a low surface tension and can easily absorb allergens and infectious organisms from air as it passes down into the lungs.

Uniquely, the cellulose powder described herein turns into a gel on contact with the moisture 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 garlic extract to Nasaleze® 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 incorporated in two countries, Finland and the United Kingdom to test whether the addition of PGE (powdered garlic extract) would increase the likelihood of preventing airborne infection amongst individuals travelling around locally and nationally during the cold winter period when airborne infections are at their peak.

METHODS

Following recruitment through advertisements in London and Helsinki daily newspapers, 52 participants were selected. A diary was designed in which each volunteer recorded general well-being for 8 weeks on a five-point scale as they travelled to and from work or on various other trips across the UK or Finland.

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 two groups of 26 participants each. A

simple random number generator assigned volunteers to the active or control group, and they were instructed to take one sniff up each nostril every day, according to the manufacturer's recommendation and if an infection was received then volunteers were instructed to take up to 3 sniffs per nostril every day that the infection was present to determine if the infectious period could be reduced in either group. Randomization codes were kept secure at the Herbal Research Centre and were not broken until all the diaries had been returned. Volunteers were contacted every 2 weeks to ensure that they were complying with the dosage regimen and that diary entries were made daily.

Diary Analysis

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

Statistical Analysis

The average symptom length in days and the average number of days challenged by a cold were subjected to calculations of standard deviation, sample variance, and standard error of the difference of the means. Data were analysed by means of a Student's *t* test to gain a probability coefficient allowing for the calculated number of degrees of freedom.

RESULTS

No participants withdrew from the study and therefore an intention to treat analysis was performed on all completed diaries. At the end of the 56 - day study, 57 major infections were recorded in the control group, but the active group recorded a total of only 20 infections. This result is highly significant (P<.001) in favour of the addition of PGE to Nasaleze® as a preventative for airborne infections whilst travelling in daily lives.

The control group had 12 serious cases where an infection lasted for 7 days whereas the active group only had 6 such cases. Similarly the number of days reported with an active infection warranting a recorded score of 3 or less in the control group was 240 days whereas in the active group this was reduced to 126 days. This result is also highly significant at p<0.05.

During the study, the 11 volunteers taking the control experienced multiple infectious episodes but this was reduced to only 2 volunteers taking the active treatment suggesting that this was indeed a preventative option.

The details of our statistical analysis indicated that the sample variance and standard deviation was low and that although the two groups were composed of mostly 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 suffered by each group so that the probability using a Students *t* test was p<0.01. Significance dropped to p<0.05 for both the number of volunteers with a serious infection lasting 7 days and the number of days reported with an active infection. However these figures clearly

	CONTROL GROUP (NASALEZE®)	**ACTIVE GROUP (NASALEZE COLD®)**
Number of active infections during the study period	57	20 p<0.01
Number of volunteers without any infection	6	10
Number of volunteers with a serious infection lasting over 7 days	12	6 p<0.05
Number of days reported with an active infection	240	126 p<0.05
Number of volunteers experiencing multiple infections during the study period	11	2

Table 1 Results of randomized blinded comparison between 2 types of Nasaleze® cellulose extract administered intra nasally.

show a difference between the groups with the Nasaleze Cold® product proving superior to the plain Nasaleze® extract.

Volunteers were also asked to record in their diaries any other concerns they had during the study, such as comments about the acceptability of taking the product, side effects, taste, or other reason that might warrant discontinuation of treatment. Generally both groups were extremely well tolerated although in the active group several volunteers (3 in total) recorded that they could easily taste the PGE although this did not stop them from continuing with the treatment.

DISCUSSION

In this pilot investigation, two inert cellulose powder formulations, both dosed intra nasally using a novel, patented delivery system were compared in a pilot randomized and blinded study to see which formulation could provide the best protection against airborne infections of indiscriminate identity. Volunteers were encouraged to go about their normal daily lives travelling around their 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 throughout the winter period and how that might be prevented.

The results were clearly in favour of the Nasaleze Cold® formulation now containing cellulose, mint and PGE (powdered garlic extract). Results indicate that a significant reduction in the number of airborne infectious pathogens picked up by volunteers was seen in this group when compared to plain Nasaleze® powder.

Examination of the volunteer diaries clearly shows that the control group suffered much more that the active group in terms of the number and duration of infectious episodes. Thus we can conclude that the addition of a potentially antiviral compound, in this case, a powdered garlic extract, can significantly reduce the number of infectious challenges that people meet during their travelling lives. The results also suggest that infection and reinfection may be effectively prevented by its daily use throughout the year, with an enormous potential savings to national industry in terms of reduced sick days. This product clearly exhibits excellent antiviral activity and warrants further investigation to determine the nature and method of its viral destruction.

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REFERENCES

1. Eccles R. Common Cold Centre Cardiff.
2. Koch and Lawson in Garlic - *The Science and Therapeutic Application of Allium Sativum L and Related Species.* Williams & Wilkins; 1996.
3. Josling PD A double blind placebo controlled evaluation of a garlic supplement in preventing the common cold *Alternatives in Therapy* Volume 18 Number 4 July/August 2001.
4. Data on file. Herbal Research Centre , East Sussex, UK.
5. Josling PD, Steadman S, Use of cellulose powder in the treatment of seasonal allergic rhinitis *Alternatives in Natural Therapy* Volume 20 Number 4 July/August 2003.