

Evaluation of ColdZyme Mouth Spray against Common Cold in Preschool Staff

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Abstract

The common cold is one of the most frequently encountered infectious diseases in humans and, despite the modest severity in most cases; it presents a significant economic burden upon society and individuals. ColdZyme® Mouth Spray (ColdZyme®, Enzymatica AB, Lund, Sweden) is a mouth spray intended to reduce the probability of catching a cold and can also help shorten the duration of a cold if used at an early stage of the infection, by forming a barrier on the oropharyngeal mucous membrane. This study evaluated the effect of ColdZyme® on common cold related sick-leave in preschool (kindergarten) staff. Fifteen preschool staff members were evaluated over a 6-month period and ColdZyme® was used according to instructions. Sick-leave days were recorded and compared to historical data. The number of average sick leave days decreased during the period from 7.4 days to 4.1 days ($p = 0.04$). It is notable that, if occurring, the majority of subjects perceived a common cold infection as milder than usual. Conclusion: Using ColdZyme® to apply a barrier to the pharyngeal mucous membrane may be an easy and practical way to prevent or reduce infections and corresponding sick leave in personnel from the preschool environment.

Keywords

Common Cold, Preschool, ColdZyme® Mouth Spray

1. Introduction

The common cold can be caused by a number of different viruses (e.g. rhinovirus, picornavirus and influenza virus) and is one of the most frequently encountered viral infections in humans [1] [2]. Colds are usually self-limiting in otherwise healthy individuals, but possible complications are recognised, such as sec-

ondary bacterial infections and exacerbation of asthma [3]. Despite the modest severity of the illness, colds can cause a significant economic burden upon society, from clinical visits to absences from school and work, including subsequent loss of earnings [4]. In general, upper respiratory tract infections account for the major fraction of all short term sick leaves [5] [6]. Epithelial cell layers in oral and nasal cavities form a physical and innate immune barrier against bacteria and viruses [7]. Yet, viruses can infect the mucosal cells in this area resulting in cold symptoms. In order to prevent infection, the natural barrier can be strengthened by applying a glycerol- and enzyme-based layer to the pharyngeal mucous membrane. This method was shown to be efficacious in a clinical study, in which the viral load decreased significantly in comparison to placebo ($p = 0.02$) and the number of days for one episode with common cold symptoms were reduced from 6.5 days to 3 days [8].

The specific conditions of preschools (kindergarten) are conducive for transmitting infectious agents. An infected child may easily propagate the virus among adult workers, parents or other contacts [9]. Consequences for infected staff often include reduced working capacity and absence from work. The objective of this study was to evaluate whether a medical device, ColdZyme® Mouth Spray (ColdZyme®, Enzymatica AB, Lund, Sweden), could be used to prevent common cold infections in preschool staff, thereby alleviating the economic burden and societal costs associated with sick leave.

2. Methods

This was a 6-month, open-label, observational study during the winter season in Sweden (October-March). Subjects were recruited among the preschool staff at a single school. Subjects having recorded sick leave absence data for the control period (October to March, preceding year) were enrolled. To reduce potential bias, officially reported sick-days were used to evaluate performance instead of using subjective symptoms related to common cold. In total, 15 adult staff members participated in the evaluation. All enrolled subjects had common cold categorized sick-leave data for the control period. The subjects were advised to use ColdZyme according to the instructions on the device. For prevention, it is recommended to spray one dose every second hour when believed being exposed to the cold virus and to obtain shortening of the duration of a cold it is recommended to start to spray one dose every second hour as soon as possible after noticing symptoms of a cold and continue until the symptoms disappears.

Short-term absences due to common cold for the treatment and control period were extracted from recorded sick-leave data at the employer. Statistical hypothesis for the analysis of sick-leave data were analyzed using paired, one-tailed Student's *t* test with a significance level of 5% [10]. A procedure for reporting any adverse events was also established. All subjects signed informed consent agreements; participation in the study was voluntary and subjects were free to withdraw their consent at any time.

3. Findings

All 15 subjects completed the study and no adverse events were reported. The average number of common cold-related sick days per subject decreased from 7.4 to 4.1 days when using ColdZyme® over a 6-months period compared to previous year (**Table 1**). The average sick-leave decreased by 3.3 days ($p = 0.04$).

To evaluate potential seasonal variances in sick-leave due to unusual low or high common cold frequencies during the treatment and control periods official data from Statistics Sweden as well as all reported sick-leave in the school management district were analyzed. The reported sick-leave according to Statistics Sweden that is eligible for sickness benefits was slightly higher for the control period compared to the treatment period, 4.75 days compared to 4.53 days respectively. The reported total sick-leave data for all personnel employed within the school management district during 2012, 2013 and January-March 2014 ($N = 70$) was 7.3%, 6.4% and 6.5%, respectively. It is concluded that neither control nor treatment period were during an unusual mild or severe cold period.

4. Discussion

This study shows that use of ColdZyme® by preschool staff might reduce short-term sick leave caused by the common cold. This reflects previous findings from a double-blind, placebo-controlled study, where subjects treated with ColdZyme® displayed a significantly ($p = 0.02$) lower pharyngeal viral load, as well as having significantly ($p = 0.01$) fewer days with common cold symptoms [8]. The current study is small with high uncertainties but notably, it seems that the preschool staff, which had on average 7.4 sick-leave days in the control period benefitted from using ColdZyme® and reduced the average sick-leave to 4.1 days.

Seasonal deviations in common cold outbreaks could explain the difference between the study results and historical data. By comparing the level of sick leave between the preschool and elementary school staff from the same school-management district, and also comparing the sick leave reported for all employed personnel in the school-management district, we concluded that a potential seasonal deviation was not responsible for the observed difference between the two cohorts.

One advantage of ColdZyme® could be that ColdZyme® is applied via the mouth to target the throat, leading to a faster reduction in viral load and a corresponding instant reduction of throat related symptoms (e.g. sore throat). Additionally, due to being applied via the mouth ColdZyme® does not interfere

Table 1. Registered sick leave due to common cold for the subjects ($n = 15$).

| | Total sick leave (days) | Mean (days) | Standard deviation | Standard error |
|------------------------------|----------------------------|----------------|-----------------------|-------------------|
| Control period ($n = 15$) | 111 | 7.4 | 7.2 | 1.9 |
| ColdZyme period ($n = 15$) | 61 | 4.1 | 4.7 | 1.2 |

with the body's natural viral defence system in the nasal passage. Instead, ColdZyme® primarily targets the oropharynx, as demonstrated in the aforementioned study that showed lower viral loads in the pharynxes of subjects in the ColdZyme® group. This suggests that Coldzyme® is able to effectively prevent infection of pharyngeal cells, which are believed to be an important area for viral replication and the progression of common cold infections [1].

Despite the modest severity of upper respiratory tract infections in most cases, the common cold can cause a significant economic burden upon society and individuals. A study by Bramley and colleagues [11] concluded that, in the USA, the economic cost of lost productivity due to the common cold approaches \$25 billion, of which \$16.6 billion is attributed to on-the-job productivity loss, \$8 billion is attributed to absenteeism and \$230 million is attributed to caregiver absenteeism. In a different study, the mean productivity loss due to common cold and allergic rhinitis in Sweden was estimated at 5.1 days or €653 per worker per year, and it was concluded that a reduction in 1 day of lost production per individual per year could potentially save €528 million [4]. Consequently, any type of intervention, preventive or therapeutic, that results in even a minor reduction in lost productivity due to decreased sick leave would be beneficial for society.

In summary, this study supports the practical everyday use of ColdZyme® in reducing the probability of infection or helping to shorten disease duration, if used at an early stage, of a naturally acquired common cold among preschool staff.

5. Conclusion

It can be concluded that applying a barrier to the pharyngeal mucous membrane is an easy and practical method to reduce transmissions of common cold viruses in the preschool environment. Use of ColdZyme® could also be beneficial to the economy and society as a whole due to the potential reduction in sick leave and associated costs.

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