



## The Comparison Efficacy of Montelukast and Echinacea as Decreasing the Incidence of Common Cold

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**ABSTRACT:** Common cold is the most common infection in children before the school aged and costs a lot yearly. The aim of doing this research is to evaluate the influence of montelukast and Echinacea in reducing the incidence of common cold between the children in 1 to 5 years old that refers to Bandar Abbas hospital. In this study, 100 healthy children between 1 to 5 years old, without any heart and lung disease were selected. The children were distributed into two groups. One group was assigned to receive Echinacea syrup (Imogen) 1cc daily and another received 4 mg muntelukast daily during 8 week. A questionnaire included age, sex, the number of catching cold, sinusitis, otitis media, pneumonia, was applied during 8 week. Parents called immediately after any sign and children were examined. Data was analyzed by SPSS19 software. Using descriptive statistics for demographic data and Chi-square Test with Fisher's exact test for Statistical Analysis. Between 100 healthy children that were studied, the average age of Echinacea group was 2.5 years and the muntelukast was 3.1 years. The rate of boys to girls was 2:1. In both groups there wasn't any meaningful difference in age and sex. In group that was received Echinacea, from 50 children 17 didn't get cold at all (34%), while in other group only 3 people didn't get cold at all. Meanwhile 19 children get cold 2 times. The average of getting cold in group of Echinacea received was one time and in other group was 2 times. In this study, it is obvious that Echinacea syrup in compare with montelukast reduces the incidence of getting common cold in children between 1 to 5 years old. But there is no influence in reducing the complication of cold. Nothing drug reaction was reported during the use of these medications. With a larger study and using placebo with these drugs and with a double blind study could receive more useful information in preventing common cold can be received.

**Key Words:** Montelukast, Echinacea, Common Cold, Prophylaxis

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### INTRODUCTION

Common Cold is the most common infection in children before the school aged. Currently, there is no effective preventive treatment for Common Cold. Common Colds are the leading reasons for people missing work or school, and they represent the leading acute diagnosis in the office setting (Cherry et al., 2007). The incidence of the common cold is highest in children younger than 5 years. Children have about 3-8 viral respiratory illnesses per year. Although Common Colds may occur year round, in the United States, most colds occur during fall and winter. Beginning in late August or early September, rates of colds increase over several weeks and remain elevated until March or April. Currently, there are no effective preventive measures for Common cold. (Douglas et al., 1986; Douglas and Hemilä, 2005). Because many viral agents may cause URI, no single vaccine is available, and because there is no known common antigen for these viruses, it is unlikely that such a vaccine will be developed. Montelukast is a selective leukotriene-receptor antagonist that inhibits the cysteinyl

leukotriene 1 receptor (Adelsberg et al., 2005). Infections with viruses causing URI, such as influenza a, rhinovirus, and respiratory syncytial virus (RSV), increase leukotriene levels in nasal secretions (Gentile et al., 2003). Echinacea plant preparations (family Composite) are widely used in Europe and North America for common colds. The majority of trials investigated whether taking Echinacea preparations after the onset of cold symptoms shortens the duration or decreases the severity of symptoms, compared with placebo. It seems that some preparations based on the herb of Echinacea purpurea might be effective for this purpose in adults, while there is no clear evidence that other preparations are effective or that children benefit (Linde et al., 2006). The study hypothesis was that prophylactic treatment with montelukast or Echinacea will reduce the incidence and severity of Common Cold in children.

### MATERIALS AND METHODS

A randomized, controlled study was performed in children between 1 and 5 years of age, who referred to

Children's Hospital of Bandarabbass. Patients were excluded if they had a previous history of reactive airways disease (defined as a history of treatment with bronchodilators in the previous 3 months or more than 1 treatment in the past year, hospital admission due to reactive airways disease, or prophylactic use of montelukast, echinacea or steroids), chronic cardiac or respiratory disease, history of allergic rhinitis, or were taking chronic medications of any kind. Patients were also excluded if there was a known allergy to montelukast or Echinacea if they had an active URI within the 7 days before consideration for the study. URI was defined as the appearance of at least 2 of the following 5 symptoms: sneezing, coughing, nasal congestion, runny nose, or fever (temperature  $>38.0^{\circ}\text{C}$ ). Duration of Cold was measured from the first day until the last day before all symptoms had disappeared for at least 2 consecutive days. In this study, the children were distributed into two groups. One group was assigned to receive Echinacea syrup 1cc daily and the received 4 mg muntelukast daily during 8 week. The primary outcome measure was the number and duration of Cold episodes. Secondary outcome measures included incidence of respiratory system infections (acute otitis media, pneumonia, tonsillitis, or pharyngitis). A questionnaire included age, sex, the number of catching cold sinusitis, otitis media, pneumonia, was applied during 8 week. Parents called immediately after any sign and

children were examined. Interventions and evaluations were completed for 100 persons. Data were entered into a database, and statistical analyses were performed using SPSS19 software. Using descriptive statistics for demographic data and Chi-square Test with Fisher's exact test for Statistical Analysis.

## RESULTS

One hundred children were recruited and randomly assigned into montelukastor Echinacea groups. Fifty children treated with montelukast and 50 of the children treated with Echinacea completed 8 weeks of treatment .The mean patient age was 3.1 years and 2.5 years in the montelukast and Echinacea groups, respectively. The rate of boys to girls was 2:1. (Table1)There were no significant differences in the clinical and demographic characteristics between the two groups.

Only 50 parents of children treated with montelukast and 50 parents of children treated with Echinacea completed the parents' diaries. For all the children who completed the study, data obtained by the research coordinator was available for all 8 weeks. In group that was received Echinacea, from 50 children ,17 didn't get cold at all (34%),while in other group only 3 people didn't get cold at all ,that,19 children of them get cold 2 times (Table 2).

**Table 1.** Age and number of Montelukast and Echinacea groups

Year	Montelukast	Montelukast	Echinacea	Echinacea
	Percent	Person (No)	Percent	Person (No)
1-2 year	10	5	10	5
2-3 year	14	7	32	16
3-4 year	28	14	26	13
4-5 year	48	24	32	16
Summit	100	50	50	100

**Table 2.** Comparison of Cold episodes in Montelukast and Echinacea groups

Cold Episode	One Cold (%) person	No Cold (%) person
Echinacea group	(66%)33	(34%)17
Montelukast group	(94%)47	(6%)3

Odds Ratio = 8; 95% Confidence Interval (2.1 to 29.7) P value  $<0.05$

The average of getting cold in Echinacea group was one episode and in other group was 2 episodes. It appears that the number of Cold was higher in children treated with montelukast compared with those in children treated with Echinacea.

In group that was received Echinacea, from 50 children 39 didn't get sinusitis at all (78%), while in other group only 41(82%) people didn't get sinusitis. It appears that there was no different between two groups.

In group that was received Echinacea, from 50 children 39 didn't get AOM at all (78%), while in other

group only 35(70%) people didn't get otitis media. It appears that there was no different between two groups. And in Echinacea group only 2 persons got pneumonia, while in other group only 1 people got it. It appears that there was no different between two groups.

## DISCUSSION

In this study of preschool-aged children, 8-week treatment with montelukast and Echinacea showed scanty reduce the incidence of Cold episodes in Echinacea group.

There were no significant differences between the groups in the number of URI complications.

Viral Cold is extremely common among infants and preschool-aged children. Cold is associated with complications such as pneumonia, otitis media, and sinusitis. Currently, there is no effective treatment of Cold. Leukotrienes are lipid mediators of inflammation, and leukotriene levels are increased in viral infections of the respiratory system. In mice infected with influenza virus, leukotriene B<sub>4</sub> levels in the lungs peaked 36 hours post infection. Interleukin 8 induces leukotriene secretion. In adults infected with rhinovirus, interleukin 8 levels in nasal secretions were significantly higher in symptomatic patients than in asymptomatic patients. There was a significant correlation between interleukin 8 and the severity of Cold symptoms. In adult asthma patients, treatment with leukotriene-receptor antagonist was associated with lower incidence of common cold-like symptoms (Kozer et al., 2012). These findings formed the basis for the rationale of the current study. We did not measure leukotriene levels in the participants, so it is not clear whether montelukast or echinacea reduced the systemic or local leukotriene levels.

Several viruses associated with upper respiratory diseases have been shown to stimulate the secretion of pro-inflammatory cytokines, including chemokines, sometimes in the absence of viral cytopathology. Rhinoviruses 1A and 14, influenza virus, respiratory syncytial virus, adenovirus types 3 and 11, and herpes simplex virus type 1, induced substantial secretion of IL-6 and IL-8 (CXCL8), in addition to several other chemokines, depending on the virus, although only viable viruses were able to do this. Echinacea inhibited this induction. The Echinacea preparation also showed potent virucidal activity against viruses with membranes, indicating the multi-functional potential of the herb (Sharma et al., 2009).

It has been postulated that montelukast may have a role in the treatment of children with otitis media (Gentile 2006). The treatment did not significantly reduce the incidence of otitis media. Although there was difference between the groups in the incidence of URI, based on parents' diaries, children treated with montelukast had more episodes of AOM and were more often treated with antibiotics. The differences between groups were small with marginal statistical significance, and their clinical implication is not clear.

In a clinical trial, prophylaxis with echinacea was associated with lower incidence of common cold-like symptoms and sinusitis (Bagher Rahmati et al., 2012). Also in several studies showed that using of Echinacea had variable effect in Cold (Weber et al., 2005; Shah et al., 2007; Barrett et al., 2010).

There are no complication during use of montelukast and Echinacea and well tolerated.

In a large, randomized, placebo-controlled study of preschool-aged children, 12-week treatment with montelukast did not reduce the incidence of Cold (Kozer et al., 2012). In our study also montelukast with comparison with Echinacea did not reduce the incidence of Cold. Beside of the results of this study, with caution we can recommend use Echinacea for prophylaxis of Cold.

Our study has several limitations. Recorded adherence to treatment was based on parental report with no objective verification. Our samples were low, thus, further evaluations with more participants are necessary to assess preventive effect of montelukast and Echinacea in Cold.

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