

**Montelukast versus inhaled mometasone for treatment of otitis media with effusion in children: A randomized controlled trial**Mohammad Bagher Rahmati<sup>1</sup>, Fatemeh Safdarian<sup>2</sup>, Babak Shiroui<sup>3</sup>, Shahram Zare<sup>4</sup>, Naser Sadeghi<sup>5</sup>

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**Type of article:** Original**Abstract**

**Background:** Otitis media is one of the most common infections among children and is a complication in about 30% of common colds. The most common complication of acute otitis media is otitis media with effusion. Some studies have reported the effects of montelukast and mometasone nasal spray in treatment of otitis media with effusion. However, current information is inadequate in this issue.

**Objective:** To compare the effectiveness of montelukast and mometasone nasal spray in treatment of otitis media with effusion in children attending Koodakan hospital in Bandar Abbas, Iran.

**Methods:** This randomized controlled trial was done on 2- to 6-year-old children attending Koodakan Hospital in Bandar Abbas, southern Iran, in 2014. Patients were divided into three groups of montelukast, mometasone, and control group. Audiometry was done for all patients at baseline and four weeks after treatment. Patients were compared for treatment results. Data were analyzed using SPSS 21.0 software.

**Results:** A total of 143 children were included in the study. Mean age of the participants were  $44.64 \pm 18.03$  months. There was no significant difference in treatment results in different treatment groups ( $p > 0.05$ ).

**Conclusion:** Mometasone and montelukast are not effective and not recommended in treatment of otitis media with effusion in children. More studies are needed in this regard.

**Trial registration:** This study is registered at ClinicalTrials.gov with ClinicalTrials.gov Identifier: NCT02541760.

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**Keywords:** Mometasone, Montelukast, Otitis media, Effusion

**1. Introduction****1.1. Background**

Otitis media is among the most common infections in children, and about 30% of common colds lead to otitis media (1). The most common complication of otitis media is otitis media with effusion (OME), which continues for four weeks in 40% and continues for three months in 10% of the patients after acute otitis media. Different treatment strategies are reported for OME, including pharmacological and surgical treatments (2-8). The results of trials on effectiveness of pharmacological treatments of OME are inconsistent (9-13).

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### 1.2. Statement of problem

Montelukast is a leukotriene antagonist, which is used in children (11). In OME, several medications are recommended, including antibiotics, antihistamines, and inhaled and oral corticosteroids, but the treatment response is controversial (9, 10, 14, 15). The efficacy of these medications in treatment of OME is limited, and the surgical treatment of tube insertion in tympan is associated with stress and needs anesthesia (16). The results of studies about the efficacy of montelukast in management of OME are controversial (11, 17-20). Some researchers have reported its efficacy in treatment of OME. Others have reported no efficacy in comparison with the placebo group.

### 1.3. Objectives

The general objective of the study was to compare the efficacy of montelukast and inhaled mometasone in treatment OME in 2- to 6-year-old children attending Koodakan Hospital in Bandar Abbas.

## 2. Material and Methods

### 2.1. Study design and setting

This study was a randomized controlled trial, which was done in the Koodakan Hospital in Bandar Abbas in 2014. This hospital is the main educational pediatric hospital in Hormozgan province, which is located in southern Iran.

### 2.2. Study population and samples

The study population consisted of 2- to 6-year-old children attending Koodakan Hospital in 2014. A total of 143 children were randomly selected to participate in the study. Patients were assigned into three groups and were followed. A flow diagram of the children in this study is shown in Figure 1.

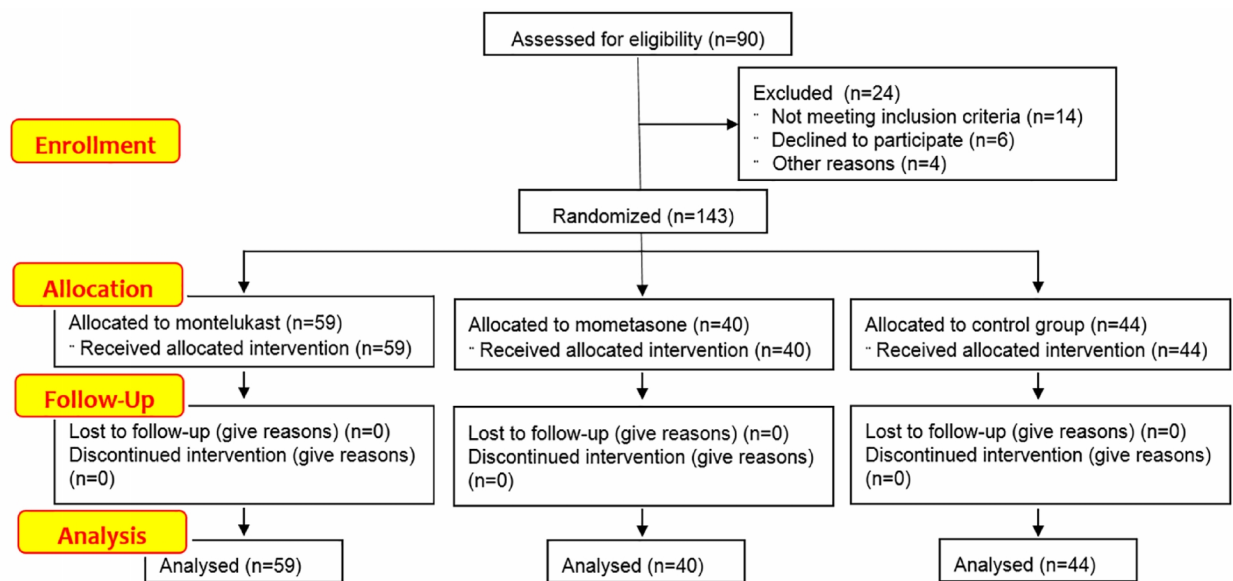


Figure 1. Flow diagram of the children enrolled in the study

### 2.3. Inclusion and exclusion criteria

The inclusion criteria in this study were 1) children between 2 to 6 years old; 2) definite diagnosis of OME with symptoms and examination. Patients were excluded from the study if they had one of the following criteria: 1) currently using corticosteroids or prophylactic montelukast; 2) chronic pulmonary or cardiac diseases or immune deficiency; 3) allergic rhinitis; 4) hypersensitivity to montelukast or corticosteroids; 5) avoidance of parents to fill the written informed consent.

### 2.4. Randomization and intervention

Participants were randomly assigned into three groups. The first group received 4 ml montelukast daily for one month, and the second group received inhaled mometasone: one puff in each side of nose for one month. The third group received no treatment.

### 2.5. Study outcomes

All patients had undergone tympanometry at the start of study and after one month to confirm the OME and to evaluate the response to treatment. Patients in each group were divided into complete improvement, partial improvement, and no improvement patients.

### 2.6. Data collection tools

Data were collected using a checklist, which included the child's general information and tympanometry, and was completed by the parents. All patients were evaluated by a physician for assessment of treatment response after one month, and the data were recorded.

### 2.7. Ethics

One of the treatments of OME is waiting treatment. Therefore, receiving no medication in the control group is not unethical. The study is confirmed by the ethics committee of Hormozgan University of Medical Sciences. The participants' information was kept confidential.

### 2.8. Statistical analysis

Data was analyzed using IBM© SPSS© Statistics version 21 (IBM© Corp., Armonk, NY, USA). For data analysis, descriptive statistics and chi-square and independent samples t-test were used. P-value less than 0.05 was assumed to be significant.

## 3. Results

### 3.1. Descriptive statistics and baseline characteristics

We studied 143 children in this study. Among them, 87 (60.8%) were male and 57 (39.2%) were female. Mean age of study participants was 44.64±18.03 months. OME was reported to be unilateral in 85 (59.4%) and bilateral in 58 (40.6%) of the study participants. The baseline characteristics of children in three groups are summarized in Table 1. As shown in this table, the patients had similar baseline characteristics. The age of the patients in inhaled mometasone was slightly higher in comparison with montelukast and the control group.

**Table 1.** Baseline characteristics of the study participants

Variables		Montelukast	Inhaled mometasone	Control group
Gender; n (%)	Male	32 (54.2%)	24 (60%)	31 (70.5%)
	Female	27 (45.8%)	16 (40%)	13 (29.5%)
Age (months); Mean (SD)		43.05±19.08	50.70±17.58	41.27±15.90
Unilateral or bilateral; n (%)	Unilateral	35 (59.3%)	23 (57.5%)	27 (61.4%)
	Bilateral	24 (40.7%)	17 (42.5%)	17 (38.6%)

### 3.2. Treatment response

Based on results of the chi-square test, three groups have no significant difference in treatment response. Details are shown in Table 2. As shown in Table 2, complete improvement was reported in 76.3%, 82.5%, and 70.5% in montelukast, mometasone, and the control group, respectively.

**Table 2.** Comparison of treatment response in study participants

Treatment response	Montelukast	Mometasone	Control	p-value
Complete improvement	45 (76.3%)	33 (82.5%)	31 (70.5%)	0.416
Relative improvement	9 (15.3%)	4 (10%)	11 (25%)	
No response	5 (8.5%)	3 (7.5%)	2 (4.5%)	

## 4. Discussion

OME is one of the common problems in children (5). Although OME can be asymptomatic, without treatment it may lead to auditory problems or learning disorders. Therefore, early treatment is recommended. Despite this, current available medications have unacceptable efficacies, and controversy exists in different research results. In this study, we have reported no effectiveness for montelukast or mometasone for treatment of OME in children. Although Aynali et al. have reported the efficacy of montelukast in treatment of OME (18), their study was done in rats and, therefore, is different from our study. Bhargava et al. have reported the efficacy of mometasone in treatment of OME in children. Their study was done on children between 2 to 12 years old, but our study was done

on children 2 to 6 years old. Also we had evaluated the children after one month, but Bhargava et al. evaluated their patients at baseline and after 8 and 24 weeks (10). Combs et al. reported the efficacy of montelukast in OME, which is different from our study, but their study population consisted of 2 to 12 year old children, which was different from our study (20). Similar results about the efficacy of montelukast in treatment of OME were reported by Ertugay et al (17). They reported the efficacy of montelukast alone or in combination with levocetirizine in treatment of OME. Their sample size were higher in comparison to our study. Some studies such as the study by Ucar et al confirms our findings that montelukast is not effective in treatment of OME (11). The study by Ucar et al is done on rats. More studies in human are needed to confirm or reject our results. One important issue in assessment of treatment response in duration of treatment. In this study we have followed the patients for one month. Longer periods of follow up may be needed to receive positive treatment response.

## 5. Conclusions

Our findings showed that montelukast and inhaled mometasone have no benefits on treatment of OME on a period of one months. We do not recommend using mometasone and montelukast in treatment of OME. However, more studies are needed to confirm our study results. Longer period of treatments may be needed in these patients.

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## Trial registration:

This study is registered at ClinicalTrials.gov with ClinicalTrials.gov Identifier: NCT02541760.

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## Conflict of Interest:

There is no conflict of interest to be declared.

## Authors' contributions:

All authors contributed to this project and article equally. All authors read and approved the final manuscript.

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