



Efficacy of a non-invasive middle ear aeration device in children with recurrent otitis media: A randomized controlled trial protocol

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ABSTRACT

Acute otitis media (AOM) represents a significant disease burden in the pediatric population. Besides vaccinations, there are no robust measures of reducing incidence of AOM in this age-group. This is a randomized controlled clinical trial evaluating the efficacy of a non-invasive middle ear aeration device, the EarPopper device (EP). We aim to investigate the reduction of episodes AOM in children with recurrent otitis media. The control arm will be observational. The intervention arm will have the EP used. The primary endpoint is incidence of AOM. The secondary endpoints are hazard ratio of time to AOM, proportion without AOM and antibiotics use, quality of life (OMO-22 Form), and adherence to treatment. Sample size is a minimum of 150 patients. The inclusion criteria is ages 4–11, with history of recurrent Acute Otitis Media (AOM).

1. Introduction

Otitis media (OM) is an inflammatory disease of the middle ear predominantly observed in the pediatric population, accounting for 10–15% of all childhood doctor visits [1]. The diagnosis of Acute OM (AOM) confers a significant incremental health-care utilization burden on both patients and the health care system. With its high prevalence across the United States, pediatric AOM accounts for approximately \$2.88 billion in added health care expense annually and is a significant health-care utilization concern [2]. Left untreated, OM can result in serious complications such as hearing loss, perforation of the eardrum, or infectious spread to the inner ear and the brain. While interventions include prophylactic antibiotics, tympanostomy tubes, and adenoidectomy, the mainstay initial treatment has been antibiotics [1]. However, there is only weak evidence that routine antibiotic treatment improves the course or prevents subsequent infections, indicating the need for an alternative solution to protect children from OM recurrence and complications [1,3].

Recent studies suggest a new device, the EarPopper, as a non-invasive treatment for middle ear effusion [4–6]. The EarPopper is indicated for the treatment of negative middle ear pressure. Negative middle ear pressure can lead to fluid accumulation in the middle ear, impaired hearing and hearing loss. The EarPopper provides a method of ventilating the middle ear by momentarily increasing the air pressure in the nose and the eustachian tube. Equalizing the pressure can prevent

the accumulation of fluid and prevent hearing loss. The EP device is 510(K) regulated (510(K) Number K073401) as a non-surgical, non-drug related treatment for middle ear pressure problems such as: Middle ear fluid (Otitis Media with Effusion), Eustachian Tube Dysfunction, Temporary hearing loss, Ear pain and pressure caused by air travel, Ear fullness caused by colds, allergies and sinusitis. The device is based on the Politzer Maneuver, and works by opening the Eustachian tube by delivering a safe, constant stream of air into the nasal cavity [7,8]. In clinical studies funded by the National Institutes of Health (Grant#: 5R44DC003613-03), the EarPopper has proven to be effective in reducing chronic middle ear effusions [4–6].

We hypothesize that the EarPopper device will be an effective prophylactic measure to reduce incidence of AOM in children with recurrent OM. Here, we present the protocol for our study, which has been approved by the Institutional Review Board (IRB) of the Northwell Health System (IRB Approval Number: 18-0388).

2. Overall design

The hypothesis of this randomized controlled trial is that the EP device will be able to prophylactically decrease incidence of AOM in children with recurrent AOM. The secondary hypothesis is that the EP device will be able to decrease morbidity of AOM and severity of AOM in children with recurrent AOM (by measuring quality of life via the OMO-22 form and associated endpoints, Table 1). This is a randomized,

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Table 1
Objectives and endpoints.

Objective	Endpoint	Justification
Primary		
To assess the prophylactic efficacy of the EP in preventing AOM	% Incidence of AOM <ul style="list-style-type: none"> Our power analysis is determined by the estimated difference in incidence between the two groups 	Our hypothesis is that prophylactic use of the EP device will decrease episodes of AOM. Therefore, we are able to assess this if we compare the % incidence of AOM in the intervention group versus the control group.
Secondary		
To assess the efficacy of the EP in reducing severity and morbidity of AOM	Hazard Ratio (HR) of time to AOM, 95% CI <ul style="list-style-type: none"> Cox proportional hazards model will be used, with or without multiple regression Kaplan Meier curves to be constructed Log rank test will be used to compare Kaplan Meier curves Proportion of patients without AOM and antibiotics	These easily obtainable data and will enable us to investigate if the EP has ancillary benefits, independent of the primary endpoint.
To assess adherence to using the device	Adherence to treatment	This endpoint acts as a control for the above endpoints, to reduce bias of the result
To assess quality of life	Quality of life, measured by the OMO-22 Form	This feedback will be used to see if there is any improvement in the quality of life between groups of patients across time

controlled, blinded study. This is a randomized controlled clinical trial evaluating the efficacy of the EarPopper device (EP) in the reduction of episodes of acute otitis media (AOM) in children with recurrent otitis media. The control arm will be observational. The intervention arm will have the EP used. Copy of schema presented in Fig. 1.

2.1. Scientific rationale for study design

The rationale of a randomized controlled trial is to test the hypothesis of reduction of incidence of AOM in children with recurrent AOM. In order to increase the robustness of the data, comparator control arm was designed in the study to compare the incidence of AOM. Control arm in this study is not a placebo control. This is because patients will be acutely aware if they are using a dummy device or not, as they will be able to notice lack of air pressure delivered by the dummy device. The baseline rate of otitis media for children age 4 and up is higher than 40%, which would therefore provide a control arm with high baseline event rate [9].

2.2. Justification for dose

The dose is twice-daily, once in the morning and once in the evening. The dose justification is based on previous randomized controlled trials featuring the EP device, which had an excellent safety profile with no longterm sequelae or side-effects [5,6]. This is the dose delivered in 3 previously published randomized controlled trials [4,5,8]. Those previous publications did not mention issues with treatment adherence, so we envision a sufficient level of adherence in our population as well. We would like to stay as close to the previously proven efficacious dose to reduce the chance of delivering a suboptimal dose. Since this is not a Phase I trial, the dose-finding aspect is beyond the scope of this study.

2.3. End of study definition

A participant is considered to have completed the study if he or she has completed all phases of the study including the last visit or the last scheduled procedure. The end of the study is defined as completion of the last visit or procedure in the trial globally.

2.4. Inclusion criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

Provision of signed and dated informed consent form from parent, plus assent form (if age appropriate); Stated willingness to comply with

all study procedures and availability for the duration of the study; Male or female, aged 4–11; Diagnosed with recurrent AOM, defined as: at least 2 episodes of AOM within the preceding year of date of screening; Must be able to follow directions to use EarPopper, or have a caregiver able to administer the device; Patient must be currently free of middle ear effusion or current acute OM. This will be determined on physical examination during screening visit.

2.5. Exclusion criteria

An individual who meets any of the following criteria will be excluded from participation in this study: Patient with chronic middle ear effusion; Patients with potential complications or confounding conditions: asthma, chronic sinusitis, immunodeficiency, diabetes mellitus; Patient with cleft palate.

2.6. Study intervention description

The EarPopper is indicated for the treatment of negative middle ear pressure. Negative middle ear pressure can lead to fluid accumulation in the middle ear, impaired hearing and hearing loss. The EarPopper provides a method of ventilating the middle ear by momentarily increasing the air pressure in the nose and the eustachian tube. Equalizing the pressure can prevent the accumulation of fluid and prevent hearing loss. The device is based on the Politzer Maneuver, and works by opening the Eustachian tube by delivering a safe, constant stream of air into the nasal cavity [7,8]. By regularly aerating the middle ear, we hypothesize that the EarPopper device will be an effective prophylactic measure to reduce incidence of AOM in children with recurrent OM. The device delivers a jet of air pressure from the nozzle at 5.2PSI, at a volume velocity of 1,524 mL/min [5].

2.7. Dosing and administration

Dose: Dosing of the EP device will be twice per day, once in the morning and once before bedtime. This is consistent with previous dosing which showed no adverse events and an excellent safety profile [5,6].

Administration: Step 1. Hold nosepiece firmly against nostril opening creating a good, tight seal is crucial. Plug the other nostril closed. Step 2. Push button to start the airflow and swallow while the device is running. Step 3. Repeat on other nostril. After 5 min, repeat steps 1–3. This will complete one treatment.

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