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ORIGINAL ARTICLE

Effects of zinc supplementation in the prevention of respiratory tract infections and diarrheal disease in Colombian children: A 12-month randomised controlled trial



N.S. Martinez-Estevez^a, A.N. Alvarez-Guevara^a, C.E. Rodriguez-Martinez^{b,c,d,*}

^a Department of Pediatrics, School of Medicine, Pontificia Universidad Javeriana, Bogota, Colombia

^b Department of Pediatrics, School of Medicine, Universidad Nacional de Colombia, Bogota, Colombia

^c Research Unit, Military Hospital of Colombia, Bogota, Colombia

^d Department of Pediatric Pulmonology and Pediatric Critical Care Medicine, School of Medicine, Universidad El Bosque, Bogota, Colombia

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KEYWORDS

Children;
Diarrhoea;
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Abstract

Background: Among the preventive strategies for lowering the incidence of upper respiratory tract infections (URTI) and acute diarrhoea episodes, two of the most common diseases in children, zinc supplementation has received special interest. However, there is a need for additional studies that determine the preventive effects of different doses of zinc on URTI and diarrhoeal disease episodes in children.

Methods: In a randomised, triple-blind clinical trial, we evaluated the efficacy of 12 months of daily zinc supplementation in the incidence of URTI and acute diarrhoea in a population of healthy children aged between 6 and 12 months living in Bogota, Colombia. The outcomes analysed were incidence of URTI, acute diarrhoeal disease episodes, and side effects of the interventions.

Results: Between 2010 and 2013, a total of 355 children underwent randomisation, with 174 assigned to the zinc supplementation group and 181 to the control group. In the multivariate analyses, having been randomised to the non-supplemented control group (IRR 1.73, 95% CI 1.52–1.97, $p < 0.001$), and nursery attendance (IRR 1.41, 95% CI 1.07–1.87, $p = 0.016$) were independently linked to the number of URTI. Likewise, having been randomised to the non-supplemented group (IRR 1.43, 95% CI 1.20–1.71, $p < 0.001$), and lower socioeconomic status (IRR 1.86, 95% CI 1.11–3.13, $p = 0.018$) were independently associated to the number of diarrhoeal disease episodes.

* Corresponding author.

E-mail address: carerodriguezmar@unal.edu.co (C.E. Rodriguez-Martinez).

Conclusions: Daily supplementation of 5 mg of zinc during 12 months significantly decreased the incidence of URTI and diarrhoeal disease episodes in a healthy population of children aged between 6 and 12 months.

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Introduction

Upper respiratory tract infection (URTI) in children is one of the most common reasons for paediatric consultations in primary care and the most common illness resulting in a decreased attendance of school.¹ Although the great majority of URTIs are self-limiting conditions and the overall risk of complications is small, they impose a great health and economic burden due to their extremely high frequency. Considering both the frequency and the mean duration of URTI symptoms, it has been estimated that an average child may have symptoms of URTI for nearly six months in the year.² Likewise, although acute diarrhoea in children is a very common, rarely life-threatening condition, it has been considered the second leading cause of death due to infections among children aged less than five years old worldwide.³ Targeted interventions to reduce the incidence and the impact of respiratory tract infections and episodes of acute diarrhoea have been considered as a necessary strategy for achieving one of the eight Millennium Development Goals, namely the reduction by two-thirds of the under-five mortality rate between 1990 and 2015.⁴

Among the preventive strategies for lowering the incidence of respiratory tract infections and acute diarrhoea episodes, zinc supplementation has received special interest.⁵ Zinc is an important trace element that must be included in the diet, because the body can neither produce it nor has adequate mechanism for storing or releasing it in case of decreased intake or increased need.⁶ Zinc is an essential micronutrient that has effect on multiple organs and systems in the human body, and is involved in over 300 biological functions, including gene expression, apoptosis and synaptic signs.⁷ Zinc deficiency, even in a low grade, may be associated with both innate and acquired immune system dysfunction,⁸ and has direct effects on the gastrointestinal tract which can lead to an increased clinical severity of acute gastrointestinal infections.⁹ This last fact is especially important for children living in low and middle-income countries (LMIC) because of the high prevalence of zinc deficiency reported in these countries¹⁰ (in Colombia it is estimated to be 43.3% in children under 5 years¹¹), and the increased zinc demand that children usually have, especially during periods of rapid growth.¹² Zinc supplementation is an effective and potentially highly cost-effective strategy that has been studied as an intervention for the treatment and prevention of respiratory tract infections and diarrhoea, especially among children living in LMIC.^{13,14} A recent Cochrane review that aimed to assess the efficacy of zinc supplementation for preventing mortality and morbidity in children aged six months to 12 years of age, concluded that supplementation reduced diarrhoea morbidity, including the incidence of diarrhoea resulting from all causes, with less precise results for respiratory tract infections.⁵ The duration of zinc supplementation in

the included studies ranged between less than two months and 12 months, and the supplement dose ranged between a daily dose of less than 5 mg and 20 mg or more. However, this Cochrane review did not include URTI data, and concluded that further research should determine the optimal characteristics of an intervention such as supplement dose. Accordingly, there is a critical need for additional studies that determine the preventive effects of different doses of zinc on URTI and diarrhoeal disease episodes. The latter is essential for planning the implementation of specific measures aimed to decrease the burden of URTI and acute diarrhoea among children living in LMIC such as the initiation of zinc supplementation and food fortification programs.

The aim of the present study was to evaluate the efficacy of 12 months of daily zinc supplementation on the incidence of URTI and diarrhoeal disease episodes in a population of children living in Bogota, a city located in a LMIC.

Methods

The study site and population

The study was conducted at Javesalud, a teaching Medical Centre located in the metropolitan area of Bogota, Colombia (2650 metres above sea level). Parents/caregivers of healthy children aged between 6 and 12 months evaluated in our general paediatric service from September 2010 to December 2013 were invited to participate in the study. Parents/caregivers of participating children were Spanish speakers, with widely varied educational backgrounds and socioeconomic status but with at least five years of elementary school. Exclusion criteria included refusal of consent, parental refusal to continue therapy, inadequate medication adherence, chronic lung disease, asthma, persistent diarrhoea, atopic dermatitis, chronic malnutrition (stunting), congenital heart disease, congenital malformations, or prematurity. Children who had been given multivitamins and/or zinc supplements within the previous three months were also excluded.

The study protocol was approved by the Pontificia Universidad Javeriana and Javesalud Research Ethics Committees in accordance with the declaration of Helsinki on the use of human material for research.

Study design and procedures

We conducted a randomised, triple-blind clinical trial designed to evaluate the efficacy of 12 months of daily zinc supplementation in the incidence of URTI and acute diarrhoea in a population of healthy children aged between 6 and 12 months. Once enrolled in the study, children were assigned randomly to the active supplementation group or to the non-supplemented control group, and observed for 12

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