

Effectiveness of monovalent rotavirus vaccine among under five year children hospitalized for acute gastroenteritis with rotavirus diarrhoea, in Central and Northern, Ethiopia: a test negative case-control study

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Background

Nowadays licensed rotavirus vaccines have demonstrated an efficacy of 85%-98% against severe rotavirus caused acute gastroenteritis and satisfactory safety profiles in large clinical trials in developed countries. However, the protective efficacy of these vaccines varies and generally is much lower rate in developing countries (pooled efficacy of 59%). Continuous vaccine performance monitoring and evaluation in real world settings is a high priority. Such monitoring will allow parents, health care providers, and decision makers to appreciate the health benefits of vaccination in reducing the burden of acute gastroenteritis caused by rotavirus. It will also allow assessment of the effectiveness of rotavirus vaccines in programmatic use and the need for modifying vaccination schedules or vaccine formulations to enhance the performance of immunization.

Objectives

The primary aim of this study is to determine the effectiveness of monovalent rotavirus vaccine since its introduction in November 7, 2013, into the national immunization program of Ethiopia. We will also characterize rotavirus genotypes that circulate in the study population and identifying potential risk factors for poor vaccine performance of monovalent rotavirus vaccine: such as poor antibody response to the vaccine and different HBGA profiles.

Methodology

A test negative case-control design will be used for this particular study. A total of 194 case patients, children less than 5 years of age (\geq six week during the first year of the vaccine introduction i.e., born after September 26, 2013), with acute gastroenteritis (the occurrence of ≥ 2 episodes of vomiting and/or ≥ 3 episodes of diarrhea, stools of a less formed character than usual, within a 24-hour period) who are laboratory confirmed stool rotavirus positive diarrhea at Gondar Hospital, Tikur Anbesa Specialized Hospital, Yekatit 12 Hospital and BeteZata Hospital, Ethiopia will be recruited. A total of 194 age-matched children hospitalized at the same hospital as case-patients with acute gastroenteritis with laboratory confirmed stool rotavirus negative will be included as control groups.

Expected outcome

The effectiveness of monovalent rotavirus vaccine will be determined and this will help in providing essential information to the Ethiopian Ministry of Health (MOH) by assessing the potential health benefits of vaccination against rotavirus, identifying host or environment related factors that might affect the performance of monovalent rotavirus vaccine and provide relevant information for other countries, with the highest disease burden, to consider introducing rotavirus vaccines within their national immunization programmes.

The study will take 2 to 3 years for completion and a total of 1,303,353.50 Ethiopian Birr is required for the completion of this research project and both AHRI and Addis Ababa University will cover the cost. The findings (results) will be presented to the scientific community and the study will be published in reputable peer reviewed international journals.

Key words: *Monovalent rotavirus vaccine effectiveness, acute gastroenteritis, rotavirus diarrhoea*