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Articles

Efficacy trial of malaria vaccine SPf66 in Gambian infants

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Abstract

SPf66 malaria vaccine is a synthetic protein with aminoacid sequences derived from pre-erythrocytic and asexual blood-stage proteins of *Plasmodium falciparum*.SPf66 was found to have a 31% protective efficacy in an area of intensive malaria transmission in Tanzanian children, 1-5 years old. We report a randomised, double-blind, placebo-controlled trial of SPf66 against clinical *P falciparum* malaria in Gambian infants. 630 children, aged 6-11 months at time of the first dose, received three doses of SPf66 or injected polio vaccine (IPV). Morbidity was monitored during the following rainy season by means of active and passive case detection. Cross-sectional surveys were carried out at the beginning and at the end of the rainy season. An episode of clinical malaria was defined as fever (â‰½37Â·5Â°C) and a parasite density of 6000/Î¼L or more. Analysis of efficacy was done on 547 children (316 SPf66/231 IPV). No differences in mortality or in health centre admissions were found between the two groups of children. 347 clinical

episodes of malaria were detected during the three and a half months of surveillance. SPf66 vaccine was associated with a protective efficacy against the first or only clinical episode of 8% (95% CI -18 to 29, p=0Â·50) and against the overall incidence of clinical episodes of malaria of 3% (95% CI -24 to 24, p=0Â·81). No significant differences in parasite rates or in any other index of malaria were found between the two groups of children. The findings of this study differ from previous reports on SPf66 efficacy from South America and from Tanzania. In The Gambia, protection against clinical attacks of malaria during the rainy season after immunisation in children 6-11 months old at time of the first dose was not achieved.

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