

Safety of purified chick embryo cell rabies vaccine (Vaxirab N) after pre-exposure prophylaxis against rabies in children

Is only adverse event profile enough?

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Keywords: children, efficacy, intradermal rabies vaccination, pre-exposure prophylaxis, purified chick embryo cell rabies vaccine, rabies, safety

Dear Sir,

We read the article recently published in your journal entitled “Pre-exposure prophylaxis against rabies in children: Safety of purified chick embryo cell rabies vaccine (Vaxirab N) when administered by intradermal route” by Ravish et al.¹ with great interest.

Rabies is still a significant cause of morbidity and mortality in developing countries.² CDC and WHO strongly recommend pre-exposure prophylaxis (PrEP) for high risk individuals living in endemic areas.^{3,4} The authors assumed that purified chick embryo cell (PCEC) vaccine is safe when administered by intradermal route for PrEP against rabies in children. However, certain points should be clarified.

First, therapeutic index is a measure of drug or vaccine safety. Therefore, safety should be determined when a drug or vaccine is known to reach clinically desired or effective dose.⁵ However, the authors claimed that their study is the first to demonstrate the safety of PCEC vaccine when administered by intradermal route for PrEP against rabies in children. Such method is a questionable approach in terms of scientific base. To our knowledge, safety of pre-exposure intradermal PCEC rabies vaccine has not been determined yet. We don't know whether intradermal PCEC rabies vaccine is effective or not. So, firstly efficacy then safety should be tested.

Second, efficacy of rabies vaccine in PrEP can be determined by studying rabies neutralizing antibodies in sera of vaccinated humans. While an antibody response of 0.5 IU/ml and above shows protectivity against rabies, values below 0.5 IU/ml can be interpreted as the absence of protective response or vaccine efficacy.⁴ Although various components of immune system are effective in vaccine response, survival after infection is mainly provided by rabies neutralizing antibodies. Studying rabies antibodies in serum is therefore essential for the detection of occurring immunity.⁶ So, vaccine efficacy could be demonstrated by studying rabies antibodies in sera of vaccinated children.

Lastly, the authors found PCEC vaccine to be safe for PrEP against rabies in children by considering only adverse event profile. However, it should be shown that vaccine had reached protective and effective level in serum.

In conclusion, it could be more pertinent to decide on the safety of intradermal PCEC rabies vaccine if the authors investigated antibody response to vaccine before investigating adverse event profile.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

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Submitted: 09/25/2013; Accepted: 10/06/2013; Published Online: 10/08/2013

<http://dx.doi.org/10.4161/hv.26716>

Response to: Ravish HS, Srikanth J, Narayana DH, Annadani R, Vijayashankar V, Undi M. Pre-exposure prophylaxis against rabies in children: Safety of purified chick embryo cell rabies vaccine (Vaxirab N) when administered by intradermal route. *Hum Vaccin Immunother* 2013; 9:1910-3; PMID:23787889;

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