A Study to Evaluate Immunogenicity of Purified Chick Embryo Cell Rabies Vaccine (PCECV) as Compared to Purified Vero Cell Rabies Vaccine (PVRV) When Administered Intradermally to Healthy Adult Volunteers in Sri Lanka

by

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Abstract

Rabies is an invariably fatal, acute viral disease and it could be prevented by immunization with a potent vaccine. In Sri Lanka, about 100 human deaths are reported annually and it is considered as one of the major public health problems with an increasing incidence of post exposure treatment (PET) per year.

Rabies vaccines developed from tissue and avian cultures are expensive. Efforts to decrease the cost of vaccination resulted in the development of the reduced dose intradermal regimens.

In Sri Lanka, World Health Organization (WHO) recommended intradermal administration of rabies vaccine was introduced in 1997 in two major hospitals and at present it is practiced in most of the hospitals in the country. It consists of giving $1/5^{th}$ the intramuscular dose, intrademally at "2-site" or "8-site" schedule.

In 2001, WHO recommended the use of 0.1 ml/dose regimen of purified vero cell rabies vaccine (PVRV), purified chick embryo cell rabies vaccine (PCECV) and human diploid cell rabies vaccine (HDCV) for intradermal PET. As a local immunogenicity trial benchmarked to the current standard is a requirement for a rabies vaccine to be introduced in a new regimen, this study was performed to evaluate the immunogenicity of the "2-site" 0.1 ml/dose Thai Red Cross-intradermal (TRC-ID) regimen of PCECV compared to the PVRV with regards to achieving adequate rabies neutralizing antibodies.

Seventy healthy adult volunteers were randomized in a 1:1 ratio into two study groups (A&B). Group A received PCECV and group B received PVRV.

Blood samples for determination of rabies neutralizing antibody titres (NAT) were drawn on days 0 (before the first dose of the vaccine) and thereafter on days 14 and 90 post-vaccination. NATs were determined by using a neutralizing test – rapid fluorescent focus inhibition test (RFFIT).

The results of the study showed that PCECV in a dose of 0.1 ml per ID injection is safe, highly immunogenic, but had a significantly less GMT at day 14 when compared to PVRV. All subjects produced rabies NATs above the WHO recommended minimum protective level of 0.5 IU/ml by day 14 which persisted until Day 90.

The preliminary results showed that this economical and simplified low-dose intradermal regimen of PCECV vaccine as an alternative schedule in rabies PET. However, before introducing the use of this schedule for PET in Sri Lanka, further studies are recommended using batches of vaccine with comparable potencies on a large study population.