Primary Vaccination of Indian Infants at 6, 10, 14 Weeks of Age with a Diphtheria, Tetanus, Acellular Pertussis, Inactivated Poliovirus, *Haemophilus Influenzae* Type B Conjugate Vaccine (Pentaxim)

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Background: Data on the immunogenicity and safety of acellular pertussis-based combination vaccines when given in the WHO recommended EPI schedule (6, 10 and 14 weeks of age) are needed for making individual clinical practice and public policy decisions in India.

Methods: This study assessed the immunogenicity and safety of primary vaccination at 6, 10 and 14 weeks of age with Pentaxim™ (sanofi pasteur, AcXim family vaccine) including diphtheria, tetanus, acellular pertussis, inactivated poliovirus, *Haemophilus influenzae* type b conjugate (PRP-T)antigens in 226 infants in India. Antibody titers were measured immediately before, and one month after, primary vaccination. Immunogenicity data from French infants vaccinated at 2, 3 and 4 months was used as a reference. Reactogenicity and safety were evaluated from parental reports.

Results: One month after the third dose, 90.0% of subjects had anti-PRP $\geq$ 1.0 μg/mL, and the GMT increased from 0.11 μg/mL to 4.17 μg/mL. Anti-Polio GMTs (1/dil U) increased from 18.1 to 441, from 20.4 to 459, and from 9.9 to 1511 for types 1, 2 and 3, respectively. Two-fold increase in PT and FHA antibody concentration occurred in 97.1% and 92.4% of subjects, and anti-PT and anti-FHA antibody titers $\geq$ 25 EU/mL were observed in 100% and 97.6% of children, respectively. The vaccine was well-tolerated, with low reactogenicity. Severe solicited reactions were documented in < 0.5% of subjects after any dose. No drop outs occurred because of adverse events.

Conclusion: Pentaxim given at 6, 10 and 14 weeks of age was well tolerated and induced large immune responses in Indian infants, similar to those observed in French infants vaccinated at 2, 3, 4 months of age in an earlier trial. [NCT00259337].

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Immunogenicity and Safety of Human Papillomavirus (HPV)-16/18 AS04 Adjuvanted Vaccine in Healthy Males Aged 10—18 Years

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Background: A human papillomavirus (HPV) 16/18 AS04 adjuvanted vaccine (*Cervarix*™, GlaxoSmithKline) has been 16/18 infections and associated precancerous lesions in 15—25 year-old women. Our study evaluated the immunogenicity and safety of *Cervarix*™ in 10—18 year-old healthy males.

Methods: This was a phase I/II, observer-blind, parallel-group study (580299/011/NCT00309166). Males were randomized (2:1 ratio) to receive *Cervarix*™ (n = 181) or hepatitis B vaccine (*Engerix-B*™, GlaxoSmithKline) (n = 89) at 0, 1 and 6 months and were followed for 7 months after the first dose.

Results: At Month 2, 100% of seronegative males in the HPV group had seroconverted for HPV-16 and 18 (ELISA) and remained seropositive at Month 7. At this time point, GMTs were respectively 4-fold and 2-fold higher, as compared to Month 2. The immune response to *Cervarix*™ in 10-18 year-old males was non-inferior for both seroconversion rates and GMTs to that seen in 15—25 year-old females in a previous study. The reactogenicity profile of the vaccine in males was similar to that reported in females. Compliance with 3-dose course was equally high (97%) in both groups.

Conclusion: *Cervarix*™ is immunogenic and well-tolerated in 10—18 year-old males, inducing anti-HPV-16 and 18 antibody responses non-inferior to those previously reported in 15—25 year-old females, among whom efficacy has been previously demonstrated. However, whether vaccination of adolescent males will ultimately prevent sexual transmission of oncogenic HPV types or have public health value remains to be determined.

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21.021

Modulation of Interleukin-18 Produces a Positive Impact on the Release of Proinflammatory and Antiinflammatory Cytokines During Malaria Infection

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Malaria infection is associated with the release of proinflammatory cytokines including TNF-alpha, IFN-gamma, IL-1, and IL-6. These cytokines play important roles in mediating the disease severity and involved in the pathogenesis and immunopathological reactions during the infection.

IL-18 is a potent pro-inflammatory cytokine and inducer of other cytokines release. In this study, we investigated the effect of modulating IL-18 production on the release of pro-inflammatory and anti-inflammatory cytokines (TNF-alpha, IFN-gamma, IL-1, IL-6 and IL-10) during malaria infection.

Plasmodium berghei infection in ICR mice was used as model for malaria infection. Mice were inoculated with parasitized red blood cells from donor mouse infected with *P. berghei*. Control animals received normal uninfected red blood cells. IL-18 production during the infection was modulated by treatment with the rIL-18, rIL-18 binding protein and anti-IL-18 monoclonal antibody. Blood samples for plasma were collected from the animals on day 1, 3 and 5 following inoculation and treatment. ELISA method