VOLUME 10 SUPPLEMENT 1 JUNE 2006 ISSN 1201-9712

International Journal of Infectious Diseases

12TH ICID ABSTRACTS

Lisbon Portugal • June 15–18, 2006

OFFICIAL PUBLICATION OF THE INTERNATIONAL SOCIETY FOR INFECTIOUS DISEASES

International Journal of Infectious Diseases

OFFICIAL PUBLICATION OF THE INTERNATIONAL SOCIETY FOR INFECTIOUS DISEASES

ckground: A multi-country, randomised, double-blind, placebo-con-lled phase IIb study(444563/006, N=2155) was conducted in nezuela, Mexico and Brazil to assess the safety, immunogenicity and icacy of two doses of live attenuated human G1P[8] rotavirus (RV) ccine(RIX4414). Results from Brazil (Belém) subset are presented re.

ethods: Healthy infants, 6-12 weeks of age at first dose, received o oral doses of RIX4414 vaccine (0-2 month schedule) or placebo con-rently with routine vaccines, except for OPV. Overall, 194, 196, 194 jects were given respectively doses of $10^{4.7}$, $10^{5.2}$, or $10^{5.8}$,focus form-units (ffu) viral concentration and 194 received placebo. During two eks after each dose infants were followed for the occurrence of fever, rrhoea, vomiting, irritability, and loss of appetite. Serum anti-rotavirus concentration (cut-off ≥20 U/ml, ELISA) was measured in a subset of infants before vaccination and 2 months post-Dose1 and 2 (serocon-sion, SC). Active follow-up for occurrence of all gastroenteritis(GE) sodes started from Dose1 up to approximately one year of infants . GE severity was determined using the 20-point Vesikari le(severe RVGE≥11). Diarrhoeal samples were analyzed for RV by SA and typed by RT-PCR.

esults: Rates of solicited symptoms and serious adverse events e similar in vaccine and placebo recipients, with no cases of intussus-tion detected. At 2 months post-Dose2, SC occurred in 54.7% to 4% of vaccinees and 10.6% of placebo recipients. As measured from eeks post-Dose2, efficacy against any RVGE at titre $10^{5.8}$, ffu was %(95%CI:21,84). For concentrations greater than $10^{5.2}$ ffu, efficacy inst severe RVGE yielded 82%(95CI%:45,95). Protection against ere RVGE caused by non-G1 rotaviruses was 81.2% (95CI%: 7,96.5), including the emerging G9 serotype.

onclusions: RIX4414 vaccine was safe, non-reactogenic, and show-good immunogenicity. At the titre of $10^{5.8}$, RIX4414 conferred signifi-t protection, particularly against severe RVGE disease.

68.015 Multicenter, Randomized, Double-Blind Study to Evaluate the Safety, Tolerability and Immunogenicity of a 2-Dose Regimen of High-Titered Process Upgrade Varicella Vaccine (PUVV®) in Subjects -13 Year of Age (VARIVAX® Protocol 049 Study Group)

Diaz[1], P. Dentico[2], R. Gonzalez[3], R. Mendez[4], S. Cinquetti[5], J.L. ben[6], L.R. Biasio[7], J.L. Silber[6], C.Y. Chan[6], R. Vessey[6], I.S.F. Chan[6], V.B. Wang[6], K. Schlienger[6], F. Schodel[6]. [1]University of Puerto Rico ool of Medicine, San Juan, PR, USA; [2]University of Bari, Bari, Italy; nsultorio de Adolecencia, Bogota, Colombia; [4]St. Vincent Medical ter, Los Angeles, CA, USA; [5]Pieve di Soligo, Treviso, Italy; [6]Merck earch Laboratories, West Point, PA, USA; [7]Sanofi Pastuer MSD, ne, Italy

kground: This study was designed to evaluate the safety, tolerabili-nd immunogenicity of 2 doses of high-titered PUVV® compared to 2 es of VARIVAX® in varicella-zoster virus (VZV) seronegative adoles-s and adults 13 years of age.

ethods: Randomized (1:1), double-blind study. Varicella history-neg-e subjects received two 0.5-mL injections, 42 days apart, of either stigational PUVV® (~50,000 PFU) or VARIVAX (~5400 PFU). ary endpoints: incidence of vaccine-related serious adverse experi-es (SAEs) within 42 days Postdose 1 and 2; percent of seronegative ects with titers 5 gpELISA units/mL at 6 weeks Postdose 2.

esults: The study enrolled 1366 subjects, including 332 VZV negative subjects. Only 1 probably vaccine-related SAE (pruritus) reported, in the VARIVAX® group. The safety profiles of PUVV® 85) and VARIVAX® (n=681) were generally similar. The proportions ubjects who reported injection-site adverse experiences during the ay follow-up after each dose were 70.0% versus 56.2% in the V® and VARIVAX® groups, respectively, and were generally mild. percentage of initially seronegative subjects with VZV antibody titers ELISA units/mL at 6 weeks Postdose 2 were similar between the 2 ps (>99.0%).

nclusion: PUVV® induces a VZV antibody response rate similar to induced by VARIVAX.® Both PUVV® and VARIVAX® are generally tolerated.

68.016 Characteristics and Classification of Osteoarticular Brucellosis

M. Bosilkovski, L.J. Krteva, E. Bosilkovska, S. Caparoska, B. Bosilkovska. Clinic for Infectious Diseases, Skopje, Former Yugoslav Republic of Macedonia

In order to make the most convenient classification of osteoarticular form of human brucellosis, demographic, clinical, laboratory characteristics, clinical course and outcome of the disease in 205 patients with osteoarticular brucellosis were examined. The patients were divided into 5 groups: (1) 37 with spondylitis, (2) 20 with concomitant spondylitis and other arthritis, (3) 35 with central arthritis, (4) 24 with concomitant central plus peripheral arthritis and (5) 89 patients with peripheral arthritis. The differences between groups were found in the patient's age, body weight, illness duration prior to diagnosis, clinical severity of the disease, defervescence, osteoarticular duration as well as therapeutic failures and sequelae. According to these findings, the most convenient classification of osteoarticular form of human brucellosis should be: spondylitis; spondylarthritis (spondylitis with concomitant other osteoarticular focus); central/mixed arthritis (central arthritis without or with concomitant peripheral arthritis); and peripheral arthritis.

68.017 Prediction of Early Virological Response—4 versus 12 Weeks of Peginterferon Alfa-2a (40KD) plus Ribavirin Treatment in Chronic Hepatitis C Patients

M. Gaseva[1], L.J. Ivanovski[1], C. Evtimovska[1], V. Grunevska[1], M. Dimzova[1], B. Tosevski[1], B. Sain[2]. [1]Clinic for Infectious Diseases, Skopje, Former Yugoslav Republic of Macedonia; [2]Medical Centre, Ohrid, Former Yugoslav Republic of Macedonia

Background: Knowledge of viral kinetics can be used to predict sustained virological response (SVR) to interferon alfa-based therapies early in the course of treatment of chronic hepatitis C. Early viral response (EVR) at week 12 of treatment is highly predictive to SVR, implying that viral load monitoring through the treatment could help guide therapeutic cost-effective regimes. How advantageable is to utilize the less used earlier prediction, rapid virological response (RVR) at week 4, to help quickly determine success of therapy.

Aims: to compare RVR with EVR of peginterferon alfa-2a (40KD) plus ribavirin treatment.

Material: 35 patients (25 male, 10 female) with chronic hepatitis C (15 genotype 1, 20 genotype 3) anti HCV and HCV RNA positive, received peginterferon alfa-2a (40KD) 180 mg/week plus ribavirin 800 or 1000/1200 mg/day depending of viral genotypes. HCV RNA levels IU per millilitre by PCR (Roche Amplicor HCV Test v 2,0) was performed at the baseline (16 high, 19 low viral load), 4 and 12 weeks and at the end of therapy.

Results: 28/35 (80%) patients had negative HCV RNA at 4 and 12 weeks and at the end of therapy. 3/35 (8,58%) showed positive HCV RNA during therapy (2 genotype 1, 1 genotype 3). 31/35 (88,58%) had positive correlations of HCV RNA results at week 4 and 12. 4/35 were positive at week 4; 2 (5,71%) of them were positive in week 12 as well, but negative at end of treatment. 2/35 (5,71%) who were positive at week 4 were negative in week 12 and at the end of treatment.

Conclusion: The results show that treatment decision should be based on an RVR at week 4 in patients treated with peginterferon alfa-2a (40KD) plus ribavirin.but to allow menagment of this earlier predictor as a clinical indicator required larger studies to confirme these results.

68.018 Observacional and Prospective Study of Treatment with Pegylated-Interferon for 12 Weeks in Genotypes 2 and 3 Pacients

R. Viana, M.R. Lopes. Santa Casa de Misericórdia de Passos, Passos, Brazil

Introduction: The hepatitis C is a kind of endemic disease in Brazil. We had 150 new cases of this disease since 2004 until now under our care and among then 57% are genotype 2 and 3.

Objective: Observe the hepatitis C treatment response with Pegylated-Interferon (PEG.INF) associated with Ribavirin for 12 weeks in patients genotype 2 and 3.