174 PROSPECTIVE EVALUATION OF RAPID DETECTION OF BACTERIAL PATHOGENS IN CSF BY COMMERCIAL COAGGLUTINATION (CoA) AND LATEX AGGLUTINATION (Latex) KITS.

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Rapid detection and identification of pathogens in bacterial meningitis is essential for prompt initiation of adequate antimicrobial therapy. Several immunologic techniques have been developed to demonstrate bacterial antigens in CSF. Two commercially available methods have become most popular because they are comparatively inexpensive and simple to perform. To assess the value of CoA (Phadebact, Pharmacia: H. influenzae b, H. influenzae a/c/d/e/f, S. pneumoniae, N. meningitidis A/B/C/Y/W135) and Latex (Slidex, Mérieux: H. influenzae b, S. pneumoniae, N. meningitidis A, N. meningitidis C), these kits were prospectively compared with the standard methods for analyzing CSF specimens from children with suspected meningitis. 206 culture- and stain-negative (Gram and methylene blue) CSF specimens resulted in specifity of 100 % for both types of reagents. With 39 culture-positive CSF specimens from patients before therapy, staining detected 37/39 =95%, CoA 34/39=87%, and Latex 21/39=54%. Cross-reaction with other bacterial antigens was observed in 7 of these samples by CoA and in 2 by Latex. With 64 follow-up CSF specimens from patients with bacterial meningitis after start of therapy, staining detected 23/64=36%, CoA 32/64=50% (cross-reaction in 13), and Latex 20/64=31% (cross-reaction in 7). Conclusions: CoA was more sensitive than Latex; however, in initial CSF specimens both kits were less sensitive than staining techniques. CoA and Latex were mainly helpful during antibacterial therapy. Cross-reactions were more frequent with CoA (esp. N. meningitidis-test). For routine use these kits are recommended only as addition to standard methods and never as replacement of standard methods.

175 ENZYME LINKED IMMUNOSORBENTASSAY (ELISA) IN THE VISCERAL LEISHMANIASIS IN CHILDREN

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As parasitology does not detect always succesfully leishmania infections,it was attempted worth to investigate the potential use of ELISA for diagnosis of visceral leishmaniasis.Specific antibodies to leishmania were searched in a) 110 healthy controls (infants and children aged 6 months to 14 years), b) 80 children clinically suspected for leishmaniasis. None of the normal children had antileishmania antibodies. In contrast all 40 children with leishmaniasis had antibodies at the time of diagnosis and 2,6 and 12 months after treatment.In 31 patients leishmanias were found in the bone marrow smear. In the remaining 9 children the diagnosis was confirmed by immunofluorescence technique,the clinical course and the positive response to specific treatment.The persistence of high antibody titres at 2 and 6 months did not correlate with the severity or the outcome of the disease.The results demonstrate that ELISA ,is a non invasive valuable supplementary method for diagnosis of leishmaniasis.

176 TWO-YEAR PROTECTION AGAINST ROTAVIRUS DIARRHOEA BY RIT 4237 ATTENUATED BOVINE ROTAVIRUS VACCINE

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The first clinical trial of RIT 4237 rotavirus vaccine indicated that one oral vaccination of infants aged 8-11 months will induce 88% protection against rotavirus diarrhoea over an epidemic season of rotavirus (Vesikari et al, Lancet i:977, 1984).

A second placebo-controlled field trial involving 347 children aged 6-12 months was started in September 1983. Postvaccination sera were collected from 328 children in December 1983 before the rotavirus epidemic season and third sera from 291 children in May 1984 after rotavirus season. A fourth serum will be collected in 1985.

Before vaccination 90% of the children were seronegative for rotavirus, and 53% of the vaccinees but none of the placebo recipients seroconverted by rotavirus ELISA-IgG. During the first rotavirus season 44% of the seronegative placebo recipients and 63% of the still seronegative vaccinees showed seroconversion indicative of primary rotavirus infection. This was associated with clinical diarrhoea in 26 cases (43%) in the placebo recipients and 4 cases (11%) in the vaccinees (p 0.001). Altogether the vaccine protection rate for rotavirus diarrhoea was 81% in the first season.

During the second rotavirus winter epidemic as of April 15, 1985, 7 cases of rotavirus diarrhoea have been diagnosed in the placebo group and 1 in the vaccine group (protection rate 85%). These results suggest that the RIT 4237 rotavirus vaccine will induce protection against rotavirus diarrhoea up to the age of 3 years.

177 EFFECT OF BREAST-FEEDING ON THE TAKE OF RIT 4237 ORAL ROTAVIRUS VACCINE

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Oral vaccination with a live attenuated bovine rotavirus vaccine strain RIT 4237 induces cross-protection against human rotavirus diarrhoea (Vesikari et al, Lancet i:977, 1984). Oral rotavirus vaccine is sensitive to gastric acid and should therefore be administered with an acid neutralizing substance such as milk. Vaccination at the time of breast feeding would be simple and logical in young infants, but breast milk might have antibodies and non-specific factors that prevent the take of the vaccine.

48 breast-fed and 58 bottle-fed (cow's milk or formula) infants aged 6 to 12 months received $10^{8.3}$ tissue culture infective doses of the RIT 4237 vaccine immediately after feeding. Serum specimens were collected before and 1 month after vaccination. Seven of the bottle-fed but none of the breast-fed infants had rotavirus IgM antibody before vaccination. Seroconversion by rotavirus ELISA-IgM antibodies was observed in 36/48 (75%) of the breast-fed and 38/51 (75%) of the bottle-fed infants. The IgG seroconversion rate was somewhat lower in the breast-fed (50%) than in the bottle-fed (69%) group. Thus in this age group breast-feeding did not inhibit the vaccine take, but possibly modified the antibody response. Altogether the serological responses were regarded as satisfactory, since it is known that the clinical protection rate against rotavirus diarrhoea is better than the serological response rate. The effect of colostrum on rotavirus vaccination is now being studied.

178 RESPONSE TO A BOOSTER DOSE OF H.influenzae TYPE B CAPSULAR POLYSACCHARIDE - DIPHTERIA TOXOID CONJUGATE VACCINE (PRP-D) IN CHILDREN INITIALLY IMMUNIZED AT 3-5-7 OR ONLY 7 MONTHS.

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22 three months old children received three doses of PRP-D at 2 months intervals, and 21 only one dose when 7 months old. In both groups half of the children received booster immunization at 14 months, and the other half at 18 months. Sera were obtained prior and post immunizations and anti-PRP antibody levels were measured by Farr-type RIA. The vaccine was well tolerated; only mild reactions were noted. The antibody responses to initial immunization have already been published (Lancet, 1985): The third dose at 7 months resulted in high antibody levels, whereas only one dose at 7 months did not. The geometric mean (GM) antibody levels before booster immunization at 14 months were 1.02 ug/ml in children who had received 3 doses of PRP-D and 0.22 ug/ml when only 1 dose had been given.

The post booster levels (GM) were 40.41, 43.56, 25.41 and 37.21 ug/ml in the four groups. All groups differed significantly from any group of children of the same age immunized with PRP only (GM levels below 1 ug/ml).

In conclusion. A PRP-D booster given at 14 or 18 months to children who were previously immunized at 3-5-7 or only 7 months was well tolerated and resulted in significantly higher antibody levels than immunization by PRP alone does. This suggests that PRP-D can induce a real booster effect.

179 HBV VACCINE IN PAEDIATRIC AGE: LONG TERM OBSERVATIONS.

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77 high risk children 0-12 years old (M=14 months ± 24 S.D.), 40 males and 37 females were selected for active immunisation against hepatitis B. 61 were newborns and infants of HBsAg positive mothers, 16 had father or other HBV carrier relatives. 60 subjects had previously received HBIG and 50/77 were still positive for passive HBsAb at prevaccinal screening. HEVAC B (Pasteur), 5 ug s.c., was given to 22 subjects at T_o-T_1- T_2 months, HBVAX (MSD), 10 ug i.m., was administered to 55/77 at T_o-T_1- T_6 months.

Clinical and serologic follow up at 2 years from the beginning of vaccination program showed:

- No complications or important side effects
- No HBV infection
- Protective titers (> 10 mU/ml) in 76/77 subjects after 2 doses (63-12400 mU/ml)
- 1 male "no responder", another male "hyporesponder" to 3 HBVAX doses and no significant increase of HB_sAb titers after the 4th dose in both cases
- Protective titers in the 32 subjects controlled at 2 ys. from the 1st dose of both vaccines and possibility of considering optional the proposed 4th dose of HEVAC B
- Sufficient protection of one HBIG dose, 0,5 ml/Kg, at birth in newborns vaccinated in the first days of life.
- Apparent better response to active immunisation in passive prophylaxed infants compared with no HBIG treated subjects as observed by Beasley and coll.