Investigational Antibody Effective Against RSV

BY PATRICE WENDLING
Chicago Bureau

TORONTO — The investigational drug motavizumab may offer high-risk infants additional protection against respiratory syncytial virus (RSV) hospitalizations in a phase III multinational randomized trial of 6,635 patients vs. 4% of 1,183 patients.

While these trends did not reach statistical significance, there was a highly significant association between higher RSV load and the need for more than 24 hours of intravenous fluids, and to not require intubation, Dr. Berkeley L. Bennett and associates reported in a poster presentation at the annual meeting of the Pediatric Academic Societies.

Higher Respiratory Syncytial Virus Load Could Be Protective

BY PATRICE WENDLING
Chicago Bureau

TORONTO — Contrary to conventional thinking, a high respiratory syncytial viral load may be protective against progression of bronchiolitis.

Elevated respiratory syncytial viral (RSV) load was unexpectedly associated with less severe bronchiolitis disease in a convenience sample of 63 children less than 2 years of age who presented to an ED with clinical signs of infection. Children with an elevated respiratory syncytial viral load were more likely to be discharged home, to require less than 24 hours of intravenous fluids, and to not require intubation, Dr. Berkeley L. Bennett and associates reported in a poster presentation at the annual meeting of the Pediatric Academic Societies.

We hypothesize that an adequate viral load is needed to induce an optimal inflammatory response.

DR. BENNETT

We included both infants who were 6 months of age or younger at the time of randomization with a gestational age of 35 weeks or fewer at birth, and children who were 24 months of age or younger with a diagnosis of chronic lung disease of prematurity requiring treatment within 6 months before the time of randomization.

It included both infants who were 6 months of age or younger at the time of randomization with a gestational age of 35 weeks or fewer at birth, and children who were 24 months of age or younger with a diagnosis of chronic lung disease of prematurity requiring treatment within 6 months before the time of randomization.

We included both infants who were 6 months of age or younger at the time of randomization with a gestational age of 35 weeks or fewer at birth, and children who were 24 months of age or younger with a diagnosis of chronic lung disease of prematurity requiring treatment within 6 months before the time of randomization.

The contraindications section also includes the statement that ceftriaxone “should not be administered concurrently with calcium-containin... products or new-borns because of the risk of precipitation of ceftriaxone-calcium salts.”

The Roche letter describes post-marketing reports of “isolated neonatal deaths” that were associated with calcium-ceftriaxone precipitates in the lungs and kidneys. In some of the cases, ceftriaxone and the calcium-containing solutions or medications had been administered by different routes and at different times.

Paticularly also can form when diltuents that contain calcium, such as Ringer’s solution or Hartmann’s solution, are used to reconstitute ceftriaxone for injection, according to the letter.

The contraindications, warnings, precautions, adverse reactions, and dosage and administration sections of the Roche label have been updated to reflect these revised recommendations. For more information, Roche can be contacted at 800-526-6367.

The approved indications for ceftriaxone include treatment of lower respiratory tract infections, skin and skin structure infections, urinary tract infections, intra-abdominal infections, acute bacterial otitis media when caused by susceptible organisms, and surgical prophylaxis.

For more information, go to www.fda.gov/medwatch/safety/2007/safety07.htm#Rocephin. Adverse reactions should be reported to Roche at 800-526-6367, or to the FDA’s MedWatch program at 800-332-1088 or www.fda.gov/medwatch.