Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: A randomized double-blinded, placebo-controlled, phase 1/11 study of the safety, reactogenicity, and immunogenicity of intramuscular inactivated influenza A/H5N1 vaccine in health children aged 2 years through 9 years (DMID 04-077)

Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov)
Authors/sponsors: John Campbell, University of Maryland; Irene Graham, St Louis University; Kenneth Zangwill, UCLA / NIAID

Study Design: 2 doses of vaccine or placebo given 1 month apart intramuscularly
Vaccine: H5N1  Manufacturer: Sanofi Pasteur, Swiftwater, PA, USA
  Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector)
  Adjuvant: none
  Delivery system/site: Needle and syringe, intramuscular, upper arm or thigh
  Doses (antigen and adjuvant): 45µg of HA in 0,5 ml given IM

Age range: Study population: child 2-9 years
Health status: Healthy children
Special inclusion/exclusion criteria: None

Clinical Endpoints Assessed
  Safety assessments: One week diary for local and systemic reactogenicity, one month after each vaccination for AEs, 6 months after last vaccination for SAEs or new chronic medical conditions
  Immunogenicity assessments:
    immunoassay type: hemagglutination inhibition and microneutralitation
    HI (type of RBC used): horse RBCs
    Neutralization (type of neutralization assay): microneutralization with detection of viral nucleoprotein in infected cells using ELISA method

Results
  Safety: vaccine is safe and well tolerated
  Reactogenicity: Infrequent redness, swelling; injection site pain and tenderness typically brief, mild
  AEs: 181 cases, 2/3 mild; most common symptoms include URI, viral syndrome, gastroenteritis
  SAEs: 2 cases, both deemed unrelated

Immunogenicity
  GMTs: after 2 doses in HI = 17, in MN = 59
  GMT Ratios (post:pre): after 2 doses GMT fold increase in HI = 3.4, in MN = 8
  Per cent responding (4 fold or greater rise and definition for reporting):after 2 doses in HI = 38%, in MN = 59%
  Per cent responders at specified titer:after 2 doses titres ≥40 in HI= 38%, in NT = 84%
  Immunization induced immune responses comparable to adults responses. Slightly better responses were detected in 6-9 year olds compared to 2-5 year old children