Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial:
Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):
Authors/sponsors: Emilia Lupulescu
Study Design: Phase I clinical trials of A/H1N1 pandemic vaccine (CANTGRIP)
Vaccine:
Manufacturer: “Cantacuzino” National Institute for Research and Development in Microbiology and Immunology Bucharest – ROMANIA, Romania
Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): H1N1 inactivated split vaccine and seasonal trivalent inactivated vaccine
Adjuvant: Al(OH)3
Delivery system/site: Intramuscular injection
Doses (antigen and adjuvant): Single dose

Study population: 112 children
Age range: 10-17 years
Health status: healthy
Specific inclusion/exclusion criteria:

Clinical Endpoints Assessed:
Safety assessments:
Immunogenicity assessments: Specific antibodies titers were determined by HI assay; in addition NN was applied. Antigens: reference strains similar to vaccine strains; in addition a wild strain H1N1 2009 isolated in our lab was included.

Results:
Safety:
Local reactions:
The highest numbers of subjects with local reactions were documented for Day 1 and Day 2 in both vaccine groups. The frequency of subjects with local reactions was lower in the pandemic vaccine group than in the trivalent vaccine group (84% and 88.1%, respectively). Overall, numbers of subjects with local reactions were remarkable during the first 2 days after vaccination as could be expected during vaccine therapy. Afterwards, only few subjects (8) had local reactions.

General reactions:
The highest number of subjects with general reactions was found at Day 3 for the pandemic vaccine group (4 subjects [8.0%]). Regarding the single days, more subjects in the trivalent vaccine group than in the pandemic vaccine group had reactions, though differences were small. Overall, more subjects of the pandemic vaccine group than in the trivalent vaccine group had reactions. However, the number of subjects with general reactions was low.

Immunogenicity
GMTs
GMT Ratios (post:pre)
Fold increase in HI after 1 dose:
16.9 with X-179A
11.8 with wild H1N1”

Per cent responding (4 fold or greater rise and definition for reporting):
HI≥4 fold increase after 1 dose:
77% with X-179A
68% with wild H1N1”
Per cent responders at specified titer:
HI≥40 after 1 dose:
94% with X-179A
92% with wild H1N1"

Others:

Status of trial (ongoing/completed): Completed