Title of Trial: Immunogenicity and Safety Study of GlaxoSmithKline (GSK) Biologicals' Influenza Vaccine(s) GSK3206641A and GSK3206640A Administered in Adults 18 to 64 Years of Age

Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov): NCT0199842

Authors/sponsors: GlaxoSmithKline

Study Design: Randomized, parallel assignment, double blind

Vaccine: H7N9
Manufacturer: GlaxoSmithKline

Type, (whole virus/subvirion/subunit/live/recombinant/DNA/vector): Inactivated split vaccine

Adjuvant:

Delivery system/site:

Doses (antigen and adjuvant):

Experimental: Formulation 1 Group
Subjects in this group will receive two doses of GSK3206641A H7N9 vaccine formulation 1 at a 21 day interval

Experimental: Formulation 2 Group
Subjects in this group will receive two doses of GSK3206641A H7N9 vaccine formulation 2 at a 21 day interval

Experimental: Formulation 3 Group
Subjects in this group will receive two doses of GSK3206641A H7N9 vaccine formulation 3 at a 21 day interval

Experimental: Formulation 4 Group
Subjects in this group will receive two doses of GSK3206641A H7N9 vaccine formulation 4 at a 21 day interval

Experimental: Formulation 5 Group
Subjects in this group will receive two doses of GSK3206640A H7N9 vaccine formulation 5 at a 21 day interval

Placebo Comparator: Placebo Group
Subjects in this group will receive two doses of placebo at a 21 day interval

Study population: 424 volunteers of 18-64 years of age

Age range: Health status: Healthy

Specific inclusion/exclusion criteria:
Inclusion Criteria:
•Male or female adults who are 18 to 64 years of age (inclusive) at the time of first study vaccination.
•Written informed consent obtained from subject.
•Subjects who the investigator believes can and will comply with the requirements of the protocol.
•Healthy subjects as established by medical history and physical examination.
• Access to a consistent means of telephone contact.
• For subjects who undergo a screening visit: results of all safety laboratory tests obtained at the screening visit must be within reference ranges. Results of any repeat testing cannot be used to qualify a subject for enrolment.
• Female subjects of non-childbearing potential may be enrolled in the study. Non-childbearing potential is defined as current tubal ligation, hysterectomy, ovariectomy or post-menopause.
• Female subjects of childbearing potential may be enrolled in the study, if they
  • have practiced adequate contraception for 30 days prior to vaccination, and
  • have a negative pregnancy test on the day of vaccination, and
  • agree to continue to practice adequate contraception until 2 months after the last dose administered.

Clinical Endpoints Assessed:

Safety assessments:
Occurrence of each solicited local symptom and each solicited general symptom
• Occurrence of clinical safety laboratory abnormalities reported for
• Occurrence of clinical safety laboratory abnormalities reported for samples
• Occurrence of Medically Attended Adverse Events (MAEs), potential Immune Mediated Diseases (pIMDs) and Serious Adverse Events (SAEs)

Immunogenicity assessments:
Humoral immune response in terms of vaccine-homologous hemagglutination inhibition (HI) antibody titers including: Seroconversion rates (SCR); Seroprotection rates (SPR); Mean Geometric Increase (MGI)

Results: Not yet available
Safety:

Immunogenicity: Not yet available

GMTs:

GMT Ratios (post:pre):

Per cent responding (4 fold or greater rise and definition for reporting):

Per cent responders at specified tite:

Others assays:

Status of trial (ongoing/completed): Ongoing