Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: Clinical evaluation of SinCon DNA-influenza vaccine

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

Authors/sponsors: Dr Dardesai/Inovio

Study Design: The phase 1

Vaccine: H5N1

Manufacturer: Inovio Pharmaceuticals, USA

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

Construct targeting A HA (from H5), NA, NP and M2eNP; Boosting: HA from H5

Adjuvant: None

Delivery system/site: Intramuscular or intradermal injections

Doses (antigen and adjuvant): 0.3 or 2, 6. Priming: two doses; Booster: single dose at least 7 months after priming

Study population: 27 adults

Age range: Health status: Healthy volunteers

Specific inclusion/exclusion criteria:

Clinical Endpoints Assessed:

Safety assessments:

Immunogenicity assessments: HI assay

Results:

Safety: No related SAEs reported (2/32 enrolled discontinued after 1 vaccination for tolerability reasons of IM)

Immunogenicity

GMTs :

GMT Ratios (post:pre):

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

≥4 fold increase after 1 or 2 doses of priming:

Intramuscular administration (after 2 doses):

96%

Ab responses persisted to > 7 months

Intradermal administration (after 1 dose):

50%
Per cent responders at specified tite:

Others assays:
Antigen specific IFN-γ ELISpot responses noted in 72% of cohort 1 and 2 participant after priming. Boosting induced HAI responses against multiple Clade 0, 1 and 2 (2.1, 2.2, 2.3.2, 2.3.4) viruses

Status of trial (ongoing/completed): Completed in 2011