Title of Trial: Safety, Immunogenicity and Productivity of a Recombinant Influenza A Vaccine Constructs
for HA1 California/07, Novel H1N1 in Healthy Adults 18-49 and ≥65 Years of Age

Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov): Objectives:
1. To assess the safety and tolerability of VAX128 in young adults and elderly adults by identifying
   the maximum tolerated dose
2. To assess the immunogenicity of VAX128 vaccine by measurement of serum HI antibody
   responses against the influenza A virus H1 HA in young and elderly adults

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Study Design:
Study Objectives:
1. To assess the safety and tolerability of VAX128 in young adults and elderly adults by
   identifying the maximum tolerated dose (MTD).
2. To assess the immunogenicity of VAX128 vaccine by measurement of serum HA1
   antibody response against the influenza A virus H1 HA in young and elderly adults

Vaccine: H1 Strain: Manufacturer: Vaxinnate Corp,
Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): HA globular head three formats of
VAX128 (A, B, C)
Adjuvant: Flagellin
Delivery system/site: Intramuscular injection
Doses (antigen and adjuvant): 0.5, 1.25, 2.5, 4, 8-12, 16, 20 µg

Study population: 112 adults
Age range: 18-49, ≥ 65 Health status: Health volunteers
Specific inclusion criteria:
Specific exclusion criteria

Clinical Endpoints Assessed:
Safety assessments Local and systemic reactions were evaluated
Immunogenicity assessments:
Immuonoassay type:
- HI Neutralization (type of neutralization assay):
Others:
Results:
Safety: It was demonstrated that the new R3 and R3.2 constructs have a better safety
profile than the c-termconstructs

Immunogenicity:
GMTs
GMT Ratios (post:pre)
Per cent responding (4 fold or greater rise and definition for reporting):
HI≥4 fold increase after 1 dose of different formats of VAX128:
89% (Format A)
83% (Format B)
89% (Format C)
Per cent responders at specified titer:
HI≥40 after 1 dose of different formats of VAX128:
83% (Format A)
83% (Format B)
86% (Format C)

Status of trial (ongoing/completed): Completed