Seasonal Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial:** Safety and immunogenicity of seasonal and pandemic inactivated whole virion influenza vaccine in healthy adults (NVI-253)

**Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):** The Netherlands National Trial Register, trial ID = 2695

**Authors/sponsors:** Renée van Boxtel, Tjeert Mensinga, Otto de Boer, Martin Friede, Willem Luytjes, Claire Boog. National Institute of Public Health (RIVM), Vaccinology Unit

**Study Design:** Phase 1, double-blind, parallel, randomized, controlled trial (N=120)

**Vaccine:**
- **Manufacturer:** Netherlands Vaccine Institute
- **Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector):** whole virus
- **Adjuvant:** none
- **Delivery system/site:** intramuscular injection in the deltoid muscle

**Doses (antigen and adjuvant):** 15 µg antigen, 1 dose, after 3 weeks a placebo dose was administered

**Study population:**

- **Age range:** Health status: 18-49 years of age, healthy

**Specific inclusion/exclusion criteria:**
- **Inclusion:** healthy adult volunteers, age 18-49 years
- **Exclusion:**
  - Previous vaccination with any vaccine in the last 3 months
  - Infectious disease with fever within the last 14 days
  - Known or suspected allergy to any of the vaccine components
  - Positive pregnancy test
  - Participation in another clinical trial in the last 3 months
  - Abnormal pre-treatment laboratory parameters

**Clinical Endpoints Assessed:**

- **Safety assessments:**
  - Solicited adverse events in diary during 5 days after each vaccination
  - Unsolicited adverse events in diary during entire study period
  - Basic safety parameters: haematology, chemistry, vital signs

- **Immunogenicity assessments:** HI titres pre-vaccination and 3 weeks post-vaccination

**Results:**

- **Safety:**
No SAEs were reported.
No fever was reported.
No clinically relevant abnormalities in basic safety parameters were reported.
Most frequent solicited AEs after vaccination: myalgia 73.3% (44/60), injection site pain 58.3% (35/60), injected limb mobility decreased 38.3% (23/60), fatigue 21.7% (13/60), injection site erythema 20.0% (12/60), headache 15.0% (9/60), malaise 10.0% (6/60).
Most frequent unsolicited AEs after vaccination: rhinorrhea 11.7% (7/60), cough 5.0% (3/60), oropharyngeal pain 5.0% (3/60), nausea 5.0% (3/60).
Most reported AEs were of mild intensity, some AEs of moderate intensity. One case of severe injection site swelling was reported and two cases of injection site induration. Also one severe case of headache was reported but this was also reported once after placebo administration.

Immunogenicity

GMTs : 788.8

GMT Ratios (post:pre): Fold increase in HI after 2 doses: 25.0

Per cent responding (4 fold or greater rise and definition for reporting): HI ≥40 or HI ≥4-fold increase after 1 dose: 91%

Per cent responders at specified titre : HI ≥ 40 after 1 dose: 100%

Others assays: n.a.

Status of trial (ongoing/completed): completed