Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial:** The study of the immunogenicity, reactogenity and safety following vaccination Pandeflu vaccine in volunteers at the age above 60 years

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

**Authors/sponsors:** Microgen

**Study Design:** Single Group Assignment, A Multi-centre, Safety/Efficacy Study

**Vaccine:**
- **Manufacturer:** Microgen
- **Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector):** subunit
- **Adjuvant:** Al(OH)$_3$
- **Delivery system/site:**

**Doses (antigen and adjuvant):** dosa - 0,5 ml, antigen – 15 mcg, adjuvant – 0,5 mg

**Study population:** 30 Healthy volunteers

**Age range:** Health status: above 60 years

**Specific inclusion/exclusion criteria:**
- **Inclusion Criteria:**
  - Age: above 60 years
  - Both genders
  - Healthy volunteers
  - Written informed consent obtained from the parent(s)

- **Exclusion Criteria:**
  - Not healthy
  - Administration of immunoglobulins and/or any blood products within the three months prior to the enrolment in this study, or planned use during the study.
  - Any confirmed or suspected immunosuppressive or immunodeficient condition based on medical history and physical examination
  - Any known or suspected allergy to any constituent of influenza vaccines

**Clinical Endpoints Assessed:**

**Safety assessments:** the local and systemic adverse events and tolerability of parenterally administered adjuvanted H1N1 influenza vaccine in all volunteers

**Immunogenicity assessments:**
- Number of Seroconverted Subjects for Antibodies Against Pandeflu
- Number of Seroprotected Subjects for Antibodies Against Pandeflu
- Seroconversion Factor for Antibodies Against Pandeflu
- Geometric Mean Titers (GMTs) of Antibodies Against Pandeflu

**Results:**

**Safety:**
the local adverse events was present in 6,7 % of volunteers (pain in an injection place)
the systemic adverse events was present in 3.3 % of volunteers (fever to 37.5 °C)

Immunogenicity

GMTs : 40

GMT Ratios (post:pre):

Per cent responding (4 fold or greater rise and definition for reporting): 80 %

Per cent responders at specified tite : 66.7 %

Others assays: Seroconversion Factor – 6.8

Status of trial (ongoing/completed): completed