Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial:** The study of the immunogenicity, reactogenity and safety following vaccination Pandeflu vaccine in children at the age of 12 – 17 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: 12 Year to 17 Years

**Specific inclusion/exclusion criteria:**

**Inclusion Criteria:**
- Age: 12-17
- 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 4 % of volunteers (pain in an injection place)
the systemic adverse events was present in 4% of volunteers (headache)

Immunogenicity

**GMTs**: 199.5

**GMT Ratios (post:pre)**:

Per cent responding (4 fold or greater rise and definition for reporting): 77%

Per cent responders at specified tite: 100%

**Others assays**: Seroconversion Factor - 5.7

**Status of trial (ongoing/completed)**: completed