Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial:** The study of the immunogenicity, reactogenicity and safety following vaccination INFLUVIR vaccine in children at the age of 6 – 17 years

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

**Authors/sponsors:** Microgen

**Study Design:** Single Group Assignment, Safety/Efficacy Study

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

**Doses (antigen and adjuvant):** 7.0 log EID$_{50}$ per 0,5 ml in two doses given at 21 days apart

**Study population:**
- 30 healthy children 12-17 ages
- 33 healthy volunteers 6-11 ages

**Age range:** Health status: 6 - 17 Years

**Specific inclusion/exclusion criteria:**
- **Inclusion Criteria:**
  - Age: 6-17
  - 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:**
- Local immune response (sIgA);
- Cells immune response (CD4+, CD8+);
- Humoral immune response (serum IgG):
  - Number of Seroconverted Subjects for Antibodies Against INFLUVIR
  - Number of Seroprotected Subjects for Antibodies Against INFLUVIR
  - Seroconversion Factor for Antibodies Against INFLUVIR
Results:

Safety:

*children 12-17 ages:*
- the local adverse events was present in 20,0 % of volunteers (hyperaemia of the fauces/arches, running nose);
- the systemic adverse events was present in 13,3 % of volunteers (headache).

*children 6-11 ages:*
- the local adverse events was present in 7,0 % of volunteers (hyperaemia of the fauces/arches, running nose);
- the systemic adverse events was absent.

Immunogenicity

*children 12-17 ages:*

Local immune response: increasing the level of sIgA by 4 times after revaccination

Cells immune response: 100,0 %

Humoral immune response:
- Number of Seroconverted Subjects for Antibodies Against INFLUVIR: 52,0 %
- Number of Seroprotected Subjects for Antibodies Against INFLUVIR: 83,0 %
- Seroconversion Factor for Antibodies Against INFLUVIR: 6,7

*children 6-11 ages:*

Local immune response: increasing the level of sIgA by 2 times after revaccination

Cells immune response: 100,0 %

Humoral immune response:
- Number of Seroconverted Subjects for Antibodies Against INFLUVIR: 59,0 %
- Number of Seroprotected Subjects for Antibodies Against INFLUVIR: 81,0 %
- Seroconversion Factor for Antibodies Against INFLUVIR: 3,0

Status of trial (ongoing/completed): completed