Research Methods

Clinical trials to test oxolin prophylactic effectiveness were carried out on 65 volunteers, who were selected based on the result of a comprehensive clinical and laboratory examination and then divided into two equal groups according to the serological data.

The control group (34 people) consisted of volunteers who received only the vaccine, the experimental group (31 people) consisted of volunteers who received the medication and the vaccine. Oxolin was administered in the form of a 0.25% ointment twice daily. Nasal mucosa smearing started 24 hours before vaccination, was repeated 30 minutes before vaccination and continued for the following 5 days.

Vaccination was carried out by administering an aerosol of standard type A2-21 live influenza vaccine with a virus concentration of 7.0 log 10. Before spraying, the vaccine was dissolved in distilled water (1 : 1) and 0.5 ml were sprayed over 5 minutes. The vaccine was atomized with a compressor producing 75% aerosol spray with the particles measuriing from 1 to 30 microns. The aerosol was inhaled through the nose and exhaled through the mouth.

Serological tests were conducted by studying paired sera taken 24 hours before and 21 days after vaccination based on a hemagglutination inhibition test (HI test).

Results

The introduction of A2 vaccine produced clinical symptoms indicating a reaction to vaccination in 48.4% of the volunteers who received oxolin and in 88.2% of the control group volunteers (P < 0.01). Thus, the administration of oxolin prevented the development of vaccinal reaction clinical symptoms in 16 out of 31 volunteers (51,6%), and the preventive effectiveness of oxolin relative to the control group was 39,8%.

Analysis of these data revealed a statistically significant difference in the severity and duration of the vaccinal reaction among volunteers in response to the introduction of a live influenza vaccine. The control group recorded mild reactions (1st degree) in 30%, moderate reactions (2nd degree) in 46.6% and pronounced reactions (3rd degree) in 23.3% of cases. The volunteers in the experimental group had no pronounced reactions, but only mild (73.3%) and moderate (26.7%) reactions were recorded.

The total duration of vaccination reactions within 1-3, 4-6 and 7-9 days among the experimental group volunteers was 46.3, 33.3 and 20% respectively (4.6 days on average) and among the control group volunteers - 10, 43.3 and 46.7% (5.9 days on average).

A distinct shortening of the duration of the vaccinal reaction among the experimental group volunteers demonstrates the therapeutic effectiveness of oxolin, which continued to be applied for 5 days after the vaccination. Analysis of frequency, severity and duration of some clinical symptoms showed that the therapeutic properties of oxolin are characterized by its local action on the nasal mucosa. Application of oxolin among the volunteers not before but after vaccination, i.e. from the time the vaccinal reaction clinical symptoms manifested themselves, alleviated the severity and shortened the duration of catarrhal symptoms (P < 0.05).

Comparative data on vaccinal fever response to the influenza vaccine injection among the volunteers of both groups showed a significant difference only in the frequency of fever rise (46.6 and 70%; P < 0.05) and did not reveal significant differences in intensity and duration of the fever response. Daily lubrication of nasal mucosa with oxolin ointment in individuals with developed vaccinal reaction did not have an effect on the frequency and duration of intoxication due to clinical symptoms such as chills, headache, aches, weakness, nausea (P < 0.05). At the same time, statistically reliable differences in the frequency, duration and severity of catarrhal symptoms were identified: nasal congestion, runny nose, sore throat, hyperemia of the soft palate and the posterior pharyngeal wall (P < 0.05).

The prophylactic effectiveness of oxolin was confirmed by the serological studies. As a result of the introduction of the A2 vaccine the number of antibodies more than quadrupled in 24.7% of the volunteers treated with oxolin and in 38.7% of the control group volunteers. The most distinct difference in the intensity of the immunological response between the experimental and control group volunteers was observed among the seronegative participants (33.3 and 100%; P < 0.05).

Conclusions

1. The lubrication of the nasal mucous membrane with a 0.25% oxolin ointment, initiated 24 hours before the vaccination of the volunteers with a type A2 live influenza vaccine aerosol, prevented the appearance of vaccinal reaction clinical symptoms in 39.8% of the participants.

2. The use of oxolin on the volunteers within 5 days after they developed pronounced vaccinal raction clinical symptoms produced a decrease in the severity and duration of catarrhal symptoms and did not affect the intensity and duration of the intoxication.

3. The use of oxolin decreased the intensity of immunological response to live influenza vaccine injection compared to the control group.