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Title: The efficacy and safety of new combined medicinal product in the treatment of influenza: The results of a multicenter randomized comparative clinical trial

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Body: BACKGROUND: Ergoferon (a release-active antibodies to interferon-γ, CD4-coreceptor, and histamine) has antiviral efficacy against pandemic influenza A(H1N1)2009 comparable to that of oseltamivir (suppression of viral replication, increase of the lifespan and reduction of the animals' mortality). AIM: To compare (vs oseltamivir) the efficacy and safety of ergoferon in the treatment of influenza. METHODS. 213 patients with flu-like symptoms (fever ≥37,8°C; at least 1 common/respiratory symptom) were examined. 52 patients with confirmed influenza received ergoferon (group 1; n=23) or oseltamivir (group 2; n=29). Primary outcome measure: percentage of participants with the body temperature ≤37,0^{0}C for 2-5 days of the treatment. RESULTS. On the 2nd day of the treatment 48% of the initially febrile patients in group 1 had the normal body temperature (vs 28% in group 2). The comparison of the two groups by the morning and evening body temperature every five days of the treatment by Cochran-Mantel-Haenszel revealed a significant difference between the two groups (χ^2=7.1; p=0.008). The severity of common and respiratory symptoms (nose/throat/chest) significantly decreased on the third day in both groups. The clinical improvement was associated with positive changes in the quality of life. Complications requiring antibiotic treatment or hospitalization were not observed during the follow-up. There were no adverse events recorded due to the drug use. No deviations in the laboratory indices were stated. CONCLUSIONS. Ergoferon is new safe drug for the treatment of influenza. Its clinical efficacy was comparable to that of oseltamivir.