P217 CLINICAL EFFICACY OF COMPLEX PHYTOPREPARATION BASED ON EVENING PRIMROSE, GENTIAN, ELDER, SORREL, VERBENA AS A THERAPEUTIC AGENT IN TREATMENT OF ACUTE VIRAL RHINOSINUSITIS IN CHILDREN

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Trial objective/hypothesis Investigation of the benefits of treatment of acute viral RS with complex phytopreparation as a basic therapeutic agent in contrast to routine therapy based on the symptomatic treatment.

Products Complex phytopreparation syrup BNO 1012

Trial design Clinical, Non-interventional, Multicentre (5 clinical centres in four cities), Prospective, Randomized, Comparative

Subjects Patients diagnosed with acute viral RS (n=169): Age: 6–11, average age 8.1; Sex: male (n=88)/female (n=81); The main group (n=94); The comparison group (n=76)

Inclusion criteria Acute viral RS; First 48 hours since onset of the disease; Severity of symptoms – 8 to 12 points on the MSS scale: nasal discharge, nasal congestion, post-nasal drip, headache, facial pain (0–4 points).

Exclusion criteria Administration of complex phytopreparation for 30 days prior to the episode; Patients diagnosed with allergic rhinosinusitis; Known intolerance to primrose drugs; More than 48 hours since onset of the disease; Severe acute disease requiring hospitalization/treatment with antibiotics; Chronic pathology and anatomical anomalies in osteomeatal complex, which may influence outcome of the disease.

Primary/Secondary efficacy criteria 1. Decrement of RS symptoms on the MSS scale; Recovery day / Reduction in frequency of transition to post-viral RS stage; Reduction in frequency of transition to purulent RS stage

Duration of treatment 14 days.

Physical examination Visit 1 (day 0); Visit 2 (day 5); Visit 3 (day 10); Visit 4 (day 14)

Patient’s self-evaluation daily for 10 days.

Conclusions Administration of complex preparation for treatment of acute viral RS among children at the age of 6–11 leads to: Substantial decrement of RS symptoms on the MSS scale starting with visit 2; There was no statistical difference between groups in terms of dynamics of ‘facial pain’ and ‘headache’ criteria, due to the toxic effects of the viral infection; Reduction of duration of disease by almost 24 hours; Substantial reduction in frequency of transition of acute viral RS to post-viral RS stage (by 79.5%) and bacterial RS stage (by 58.7%).