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Clinical Evaluation Of A New Approach In Acute Rhinosinusitis

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Introduction:

It is currently estimated that 14% of the US population is affected by an episode of rhinosinusitis, afflicting all age groups and all segments of the population. Lyophilized extract of *Cyclamen europeum* nasal spray is a new treatment that facilitates physiological drainage and cleansing of the paranasal cavities through the mucous membranes. The objective of the clinical trial was to evaluate the efficacy and safety of this product in patients diagnosed with moderate to severe acute rhinosinusitis.

Methods:

A randomized, double-blind placebo-controlled trial was conducted in patients with acute rhinosinusitis. All patients received antibiotics during 8 days as base treatment. Efficacy was assessed at 2 weeks by patient reported symptoms (nasal obstruction, nasal secretion, facial pain, loss of smell) using a visual analogical scale. Mucous oedema and mucopurulent secretion was measured by endoscopy. Patient and Investigator satisfaction with treatment was evaluated. Safety evaluation was performed by reporting adverse events.

Results:

99 patients were randomized (Cyclamen:48, Placebo:51). Study groups were homogeneous on demographic and clinical baseline data. The analysis shows statistically significant differences between means of facial pain (-1.2 with CI 95% from -2.3 to -0.1; $p=0,036$). Cure of endoscopic signs was higher ($p=0,043$) in Cyclamen (48,7%) than placebo (30,9%). Both patient ($p=0,0327$) and investigator ($p=0,0324$) satisfaction were in favor of Cyclamen. No serious or unexpected adverse events were reported.

Conclusion:

Cyclamen europeum is a new therapy suitable in acute rhinosinusitis treatment that has demonstrated its efficacy and safety.