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SUMMARY OF PRE-CLINICAL STUDY REPORT

Nosiboo Pro Clinical investigation

QP21-NO10_Nosiboo PRO-2023-2

Description of the study: A prospective, randomized study, investigation on the performance and safety of the Nosiboo Pro nasal aspirating medical device for children with acute inflammatory disease in the upper respiratory track, to demonstrate that the use of the Nosiboo Pro device can reduce the incidence of superinfections.

Conclusion: When using the Nosiboo Pro nasal aspirator, it can be stated that children aged between 6 months to six years have a higher rate of recovery from viral infections and common colds when using nasal aspiration compared to children who do not use nasal aspiration. The Nosiboo Pro nasal aspirator has been proven to be effective, safe, and tolerable as a primary or supplementary therapy for treating common cold symptoms of infants and toddlers unable to blow their noses.

Type of study: Prospective, randomized, non-interventional study

Test device: Nosiboo Pro nasal aspirating medical device

Primary objective: Proving that the use of Nosiboo Pro for children with acute inflammatory disease in the upper respiratory track can reduce the incidence of superinfections.

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Secondary objective: Demonstrating that supplementary treatment by Nosiboo Pro of acute inflammatory disease in the upper respiratory tract alleviates the course of the disease.

Number of Study Participants: 50 children aged between 6 months to 6 years with common cold and viral infection.

Detailed results:

Efficiency: In the treatment group without nasal aspiration, the cure rate was 56.0% (n=14), whereas in the treatment group with nasal aspiration, the cure rate was 88.0% (n=22). In contrast, the proportion of non-cured patients in the treatment group without nasal aspiration was 44.0% (n=11), compared to 12.0% (n=3) in the treatment group with nasal aspiration. The results of the Fisher test showed that there was a statistically significant correlation between the treatment group and the study outcome, with a higher proportion of cured patients in the group using nasal aspiration (p=0.025).

Safety: Instrument failure did not occur at all during the study. There was no nosebleed. During the treatment, in 100% of the cases there was no itching, burning, stinging, tension, or tingling.