

SUMMARY OF PRE-CLINICAL STUDY REPORT

Nosiboo Pro Clinical investigation

QP21-NO11_Nosiboo PRO-2021-1

Description of the study: Study of the efficacy and safety of the Nosiboo nasal aspirator as a medical device in small children with a common cold and nasal congestion.



Conclusion: The Nosiboo Pro nasal aspirator is an effective and safe device that is simple and easy to learn to use. Thus, the use of the device between the ages of 6 months and six years 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: non-interventional, observational study

Test device: Nosiboo Pro nasal aspirating medical device

Primary objective: To determine the extent to which the use of Nosiboo Pro improves the airway resistance of the nasal passages of a child with a nasal congestion as measured by a rhinomanometer.

Number of Study Participants: 49 children aged between 6 months to 6 years with a common cold.

Detailed results:

Efficiency: In the study, 100% efficacy was observed, with all 49 children who were selected and treated having successful nasal aspiration, according to the data collected. Using the Nosiboo Pro device as intended can result in a measurable change in nasal airflow.

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.

Usability: For ease of use of the device, 73.5% of the devices received a maximum rating, 24.5% received a rating of 4, and 2% received a rating of 3 on the 5-point Likert Scale.