

SUMMARY OF PRE-CLINICAL STUDY PROTOCOL

Description of the study: Study on the efficacy and safety of Nosiboo Pro, Pro2, and Go medical devices in simulated nasal congestion. Demonstrating that nasal aspirators operating based on air flow principle are able to aspirate quantitatively more secretion than nasal aspirators operating based on vacuum principle.

Conclusion: Nosiboo Pro was able to aspirate an average of 83% of the 6.5 g sample material from the modelled nasal cavity, making it the most effective of the devices tested. Nosiboo Go followed with slightly less, 69%. The other devices included in the study aspirated 39% and 42% of the sample material on average. The latter two nasal aspirators work with higher vacuum pressure but significantly lower airflow. However, the advantage of nasal aspirators based on air flow, such as Nosiboo products, lies in their ability to aspirate secretions from the sinuses more efficiently, as we have seen in the example of our anatomically detailed model.

Type of the study: Laboratory (pre-clinical) study, simulated nasal aspiration using a 3D model.

Test device: Nasal aspirating medical devices Nosiboo Pro/Pro2/Go in electric desktop and portable versions.

Primary objective: Study on the efficacy and safety of Nosiboo Pro/Pro2/Go nasal aspirating medical devices in simulated nasal congestion.

Secondary objective: Demonstrating that nasal aspirators operating based on air flow principle are able to aspirate quantitatively more secretions than nasal aspirators operating based on the same vacuum value (vacuum principle).

Detailed results:

Efficiency: The Nosiboo Go and Pro products using the air flow principle can remove significantly more secretions from a scale model of the sinus cavity than conventional devices based on vacuum technology. The measured values confirm that Nosiboo Go and Pro nasal aspirators were able to achieve this at lower pressure (vacuum) and significantly higher airflow indicators compared to conventional devices.