

A Disposable Device NAS to Treat Obstructive Sleep Apnea and Snoring

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Statistical Analysis Plan

The primary endpoint that will be evaluated in the study would be the AHI efficacy of the NAS device by PSG comparisons. The PSG factors concerned will be compared between the two PSG evaluations conducted, the initial control PSG evaluation without the NAS device applied and the PSG evaluation with the NAS device applied.

As for the questionnaires, each questionnaire such as the ESS, the BQ, the MQ, the SSS, the SAQLI and etc., obtained will be analyzed for determining qualitative factors regarding quality of life and sleep qualities. In addition, these questionnaires and interviews will be valuable resources regarding safety issues as well.

The secondary endpoint that will be evaluated in the study would be the safety of the NAS device. Interviews and questionnaires would be the mode of evaluation regarding the safety factors. The ultimate goal of safety would be finishing this clinical study without any adverse events or accidents that harm the subjects physically.