AUDISTIM® Day/Night Alleviates Tinnitus-Related Handicap in Patients with Chronic Tinnitus: A Double-Blind Randomized Placebo-Controlled Trial

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Purpose of the study

This study aims to evaluate the efficacy of taking a daily supplement based on active compounds (AUDISTIM® Day Night: A D/N) in alleviating tinnitus-related disability as suggested by previous real-life studies (1,2).

Objectives

The study methodology is as described by Kikidis et al. (3), and follows the latest recommendations for ran- domized controlled trials on tinnitus in tinnitus. Changes in THI score at 3 months was chosen as primary endpoint.

Materials and methods

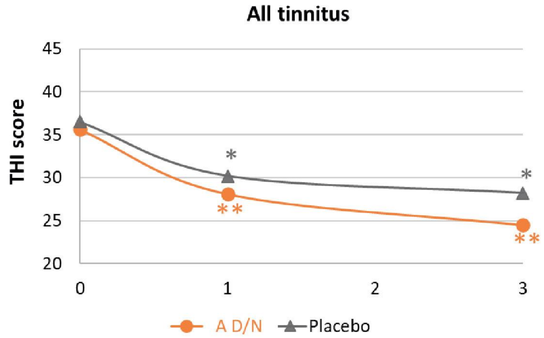
This double-blind randomized placebo-controlled study was conducted in adults with mild to severe tin- nitus receiving a 3-month supplementation with A D/N (magnesium, vitamins, phytochemicals) or placebo (excipients without active ingredients). Tinnitus-related handicap (THI), psychological stress (MSP-9), and sleep quality (PSQI)) (4-7) were assessed at baseline and during intervention, perceived impression of tinnitus improvement at the end of the follow-up. All clinical investigation, data collection, assessments, and data analyses were blinded to randomization allocation.

The sample size assumed a 10-point difference in the mean change at M3 in THI scores between A D/N and placebo. The sample size reached 98 subjects (49 per arm), increased to 110 subjects in total to account for dropouts.

Statistical analysis were conducted according to the Statistical Principles for Clinical Trials ICH-E9 guidance (8).

Results

The full set analysis included 114 patients (59A D/N, 55 placebo) aged 53.8 ± 11.4 years, 58% women, with fluctuating (45%) or permanent (55%) tinnitus from 9.3 ± 9.4 years. A D/N supplementation led to greater changes in THI (−13.2 ± 16.0 vs. −6.2 ± 14.4, p = 0.0158, Cohen's d = 0.44) at 3 months (primary outcome), especially with continuous tinnitus (−15.0 ± 16.3 vs. −4.6 ± 12.8, p = 0.0065), and, to a lesser extent, at 1 month (−9.8 ± 13.1 for A vs. −4.3 ± 12.1, p = 0.0213). PSQI significantly improved over time in both groups, but MSP-9 only with A D/N.



Conclusion

In lines with previous observational studies, both clinical (THI score > 7 pts) and statistical (vs. placebo) improvement, more pronounced in permanent tinnitus, demonstrate the effectiveness of the combination of active compounds and support its use in the management of mild to severe tinnitus (9).

References

1 Frachet B et al 2017. 2 Van Becelaere T et al 2019. 3 Kikidis D. et al 2021. 4 Newman CW et al 1998. 5 Zeman F et al 2011. 6 Lemyre L et Tessier R 2009. 7 Buysse DJ 1989. 8 ICH Harmonised Tripartite Guideline E9 1998. 9 Portmann D et al 2024.