

# **Double blind study for Low Level Laser Therapy in patients with chronic cochlear dysfunction**

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## Clinical phase III study

- Prospective, randomized, double blind study
- 175 patients (72 females, 103 males)
- Mean age  $51.5 \pm 13.4$  years
- Chronic persistent cochlear tinnitus (3 - 300 months)
- 3 treatments at time intervals of 2 weeks:

$\lambda$ [nm]	Dose $\text{J}/\text{cm}^2$	ext. Dose [J]	Patients
Placebo	-	-	59
635	4	4 - 40	21
690	12	6 - 30	40
780	65	16 - 65	29
830	100	25 - 100	26



# Evaluation

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## Time schedule:

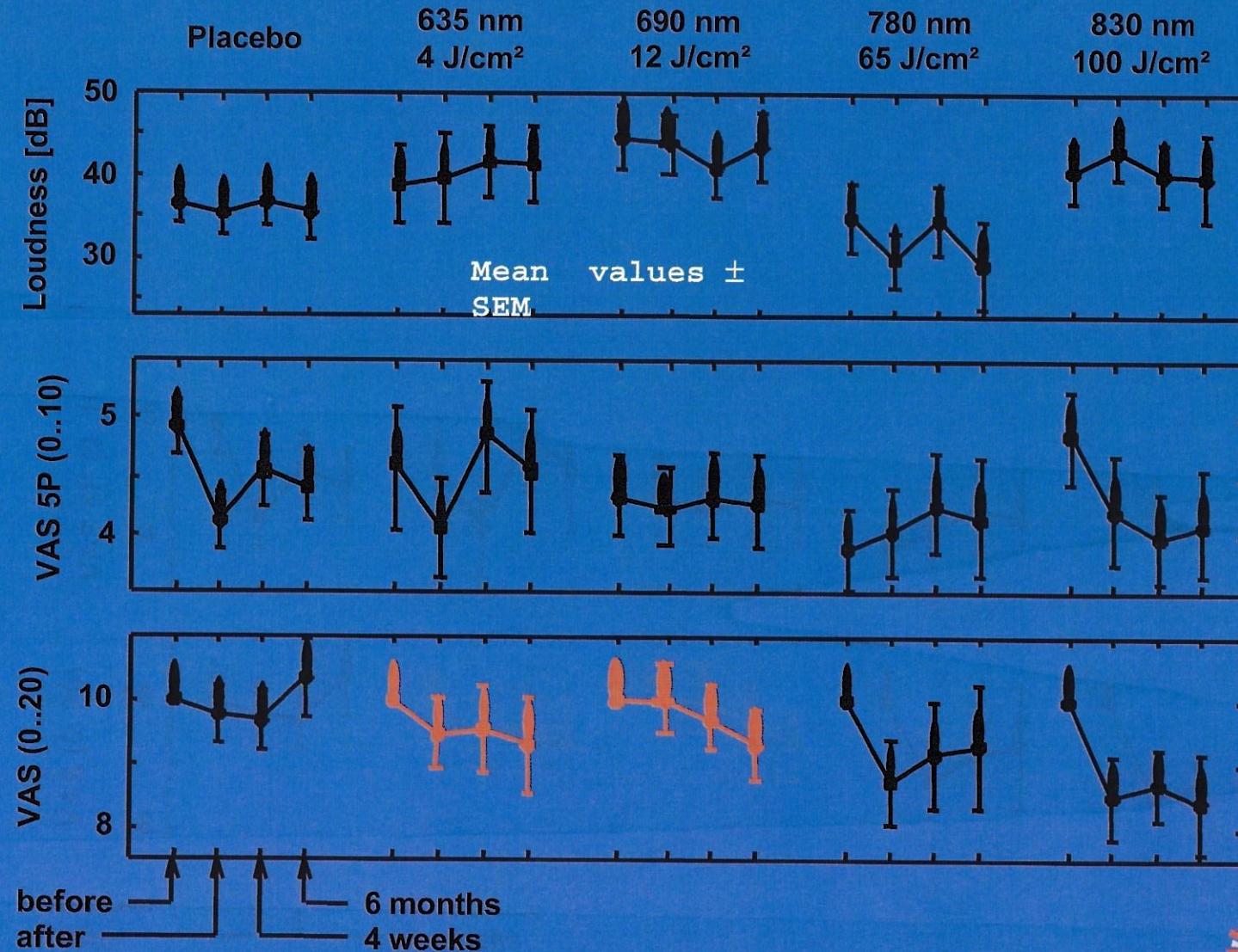
- Before first treatment
- After last treatment
- 4 weeks after last treatment
- 6 months after last treatment

## Tinnitus and audiometric assessment:

- Loudness [dB] via noise matching
- VAS (visual analogue scales; 0 .. 10) for 5 parameters: loudness, inconvenience, control, disposition, stress
- Total tinnitus score VAS (tinnitus 0 .. 20, initial value: 10)
- *Goebel-Hiller-Score (not yet evaluated)*
- *Hearing threshold (not yet evaluated)*



## Preliminary results



## Summary

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- Double blind, randomized, prospective study
- Dosimetry is specific for acoustic frequency
- No side-effects
- Tendency of tinnitus improvement at 690-830 nm (VAS 5 P) and at 635-830 nm (Total VAS score)
- Chance for possible effects at higher light doses (65-100 J/cm<sup>2</sup>)
- Significant effects for special sub groups?
- Further statistical analysis is on work

