



High Intensity Focused Ultrasound (HIFU) a novel treatment modality for skin lesion: Preliminary results from a prospective dual-center clinical investigation on cutaneous neurofibromas.

Katrine E Karmisholt, MD, PhD

Objectives: The objectives of this study were to investigate safety, local tolerability, and efficacy of high intensity focused ultrasound (HIFU) for cutaneous neurofibroma (cNF). cNFs are benign intradermal tumors that can appear in numbers up to several hundred on the skin of neurofibromatosis (NF1) patients

Introduction: High intensity focused ultrasound (HIFU) is capable of controlled and targeted thermo-mechanical treatment to intradermal volumes, without inflicting damage to the surrounding tissue and leaving skin surface without scarring. This treatment modality may be useful for benign and premalignant skin lesions.

Materials / method: Twenty cNF patients were recruited in Copenhagen and Gothenburg centers. Focused ultrasound treatment utilizing a 20 MHz HIFU-device with integrated dermoscopic guidance was performed using a handpiece with a focus depth of 2.3 mm below the skin surface. Single dose acoustic energy of 0.7 J/dose of pulse duration 250 ms/dose was manually positioned until the full cNF was covered. No anesthetic was applied. Primary endpoint was evaluation of safety and tolerance of the HIFU-treatment. Clinical efficacy was reported at 9 months follow-up.

Results: A total of 147 cNFs (diameter 2-9 mm) were treated. Mild wheal-and-flare reaction was observed immediately after treatment. Occasionally, erosions/crusts were observed and rarely dyspigmentation after 1 week and 3, 6 and 9 months post-treatment respectively. No serious adverse events occurred, and no significant scarring was observed. Visual rating of treated cNFs by the clinical investigator at 9 months showed that 45 out of 92 cNFs (49%) had full or substantial reduction. During treatment the patient-reported pain-score was median 3.5 (range 1-7) on a 10 point scale

Conclusion: HIFU treatment is a new non-invasive, rapid, and tolerable treatment modality. This study demonstrates the safety, local tolerability, efficacy, and feasibility of HIFU for the treatment of cNFs. Further studies may open for this new treatment modality to remove other benign, premalignant or even malignant skin lesions.

Full list of Authors:

K E Karmisholt¹, J Serup¹, M Tang^{2,3}, M Gillstedt^{2,3}, J O Blakeley⁶, J Roberts⁶, T Bove⁷,
S Peltonen^{2,3,4,5}

¹Department of Dermatology, Bispebjerg University Hospital, Copenhagen, Denmark

²Department of Dermatology and Venereology, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden.

³Region Västra Götaland, Sahlgrenska University Hospital, Department of Dermatology and Venereology, Gothenburg, Sweden

⁴Department of Dermatology and Allergology, University of Helsinki

⁵US Helsinki University Hospital, Department of Dermatology and Allergology, Helsinki, Uusimaa, Finland.

⁶Neurofibromatosis Therapeutic Acceleration Program (NTAP), Department of Neurology, Johns Hopkins University School of Medicine, Baltimore, Maryland, USA

⁷TOOsonix A/S, Hoersholm, Denmark