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Safety and efficacy evaluation of an isotonic manganese-enriched seawater solution on human nasal epithelium reconstituted in vitro

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Statement of the Problem: Nasal irrigation with saline solutions is frequently used for relief of rhinitis symptoms. Literature suggests that manganese (Mn) contributes to a decrease in allergic nasal response. In vitro research studies were conducted on 3D model of airway epithelium to evaluate efficacy and safety of a Mn-enriched seawater solution called Stérimar Allergic Nose (SAN).

Methodology: The 3D Reconstituted Human Nasal Epithelium model (RHNE) was treated with 10 μ L of SAN twice a day for four days to simulate repeated use (full strength) or untreated (control). For epithelium integrity (safety), the control and SAN-treated cultures were analyzed for: Trans-Epithelial-Electrical-Resistance (TEER) on days 1 (D1) and 4 (D4) post-treatment, and release of Lactate Dehydrogenase (LDH) and Interleukin 8 (IL-8) daily from D1 to D4. For efficacy, Mucociliary Clearance (MCC) and stimulation of epithelium-regeneration were assessed. MCC was measured by video-microscopy on D1 and D4 after the same treatment regimen. For epithelium-regeneration, RHNE was treated with 30 μ L of SAN or saline. After a glass capillary injury, made 1 hour after treatment, regeneration stimulation was assessed as a percentage of wound closure by comparative photography immediately after the injury and 2, 6, 22 and 30 hours later.

Findings: SAN showed an average TEER of 302 and 323 ohm.cm2 (p<0,001) on D1 and D4, respectively, safely above tissue integrity limit (100 ohm.cm2). LDH and IL-8 releases were similar for SAN and control at all-time points, also confirming epithelium integrity and safety. SAN showed a significant MCC increase as compared to control (P<0.01). Furthermore, SAN showed faster and greater wound closure than control (86.59% for SAN versus 50.65% at 22 hours).

Conclusion: SAN demonstrated efficacy and safety in the in vitro assays. The results support the use of Mn-enriched SAN in relief of rhinitis symptoms.

Biography

Barbara De Servi has obtained a Biology degree at the University of Milan in 1998 and in 2002, she obtained PhD in Physiopathology at University of Milan and at DKFZ, in Heidelberg. In 2005-2006, she was Post-Doctoral Fellow at the University of Verona Medical School. Since 2007, she is the Study Director at VitroScreen, in charge to develop tailor-made "omics" research models and identify toxicity pathways on 3D human tissue models.

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