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Topic of Presentation: Phase 1 and 2 clinical trials of CPNE7-derived peptide

(Selcopintide) for dentin hypersensitivity

Abstract:

Copine7 (CPNE7) is known to induce odontoblast differentiation and tertiary dentin formation, and thus has the potential to be used as a therapeutic agent for dentin hypersensitivity. CPNE7-derived functional peptide (Selcopintide), which replicates the function of CPNE7 has been developed for better stability and manipulation. Randomized, double-blind and placebo-controlled phase 1 and 2 clinical trials were carried out to assess the safety, tolerability, efficacy and pharmacokinetics of Selcopintide solutions in dentin hypersensitivity patients from June 2021 to September 2024. Safety was evaluated with physical and oral examinations, vital sign and ECG check, clinical laboratory test and adverse event collection. Efficacy was assessed by evaluating change from baseline in ice-cold water measured by visual analogue scale (VAS), in evaporative air sensitivity as measured by Schiff sensitivity score, and in tactile threshold. The subjects were also hospitalized for pharmacokinetic blood analysis. The results showed that all adverse events were transient and recovered, without any alterations or withdrawals of the drug, and no serious adverse events occurred. No Selcopintide concentrations were detected at any point of pharmacokinetic blood samplings of all subjects. Furthermore, when applied multiple times, Selcopintide showed tendency to reduce dentin hypersensitivity. In conclusion, Selcopintide is safe, well tolerated and shows effectiveness when applied to exposed dentin at doses up to 10ug/tooth. A Phase 3 clinical trial is planned to further evaluate its efficacy.