Tilmelding af Foredrag

Foredragets titel

Mesenchymal Stem/Stromal Cell Therapy for Radiation-Induced Xerostomia in Previous Head and Neck Cancer Patients: A Phase 2 Randomised, Placebo-Controlled Trial

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Uddannelsesniveau

MD

Introduktion

No effective treatment exists for radiation-induced xerostomia. The objective of this study was to compare the effect of adipose-derived mesenchymal stem/stromal cell (ASC) injection, relative to placebo, on salivary gland function in patients with radiation-induced xerostomia.

Materiale/metode

In this single-centre, double-blind, placebo-controlled trial, patients with hyposalivation were randomised to receive ultrasound-guided injections of allogeneic ASCs or placebo into the submandibular glands. Patients were followed for four months. We evaluated unstimulated whole salivary flow rate (UWS), stimulated salivary flow rate, and patient-reported outcomes. Adverse events were recorded and immune response determined in blood samples.

Resultater

We enrolled 120 patients. ASC treatment resulted in a statistically significant UWS increase of 0.04 [95% CI 0.02 to 0.06] mL/min (38%) compared to pre-treatment baseline whereas placebo treatment did not cause a significant increase (0.01 [-0.01 to 0.04] mL/min (21%)). Both the ASC and placebo treatment yielded notable symptom reductions, with dry mouth decreasing by 13.6 units and 7.7 units, sticky saliva decreased by 14.8 units and 9.3 units, swallowing difficulties decreased by 7.9 and 8.0 units, and the summary score of the Xerostomia Questionnaire decreased 5.9 units and 5.1 units for the ASC and placebo-arm, respectively. We found no statistically significant group difference between the ASC and placebo-arm for any of the outcomes.

Diskussion

We could not confirm superiority of the ASC relative to placebo. ASC therapy significantly improved UWS in previous

head and neck cancer patients, whereas placebo resulted in an insignificant increase.

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