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Phase I Study of Novel Radioenhancer NBTXR3 Activated by Radiotherapy in Cisplatin-Ineligible Locally Advanced HNSCC Patients

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Purpose/Objective(s): Concurrent radiotherapy (RT) with high-dose cisplatin, or cetuximab in case of intolerance to cisplatin, are the non-surgical standard treatment for locally advanced head and neck squamous cell carcinoma (LA HNSCC). However, elderly patients, patients with poor performance status, comorbidities, and/or intolerance may not benefit from these treatments and represent a high unmet medical need. New approaches are thus needed to improve the patient clinical outcomes without adding toxicity. NBTXR3, composed of functionalized hafnium oxide nanoparticles, is injected once intratumorally and activated by RT. NBTXR3 increases the RT energy deposit inside tumor cells and subsequently increases tumor cell death compared to RT alone, without adding toxicity to healthy tissues. We present here current results of the dose expansion part of the phase I study evaluating NBTXR3 plus intensity modulated radiation therapy (IMRT) in this population (ClinicalTrials.gov: NCT01946867).

Materials/Methods: Patients with stage III-VA or T3/T4 (AJCC/UICC TNM staging system 8th ed.) HNSCC of the oropharynx or oral cavity, ineligible to cisplatin or cetuximab and amenable for RT, received a single intratumoral injection of NBTXR3 and IMRT (70 Gy in 35 fractions /7 weeks). A classical 3 + 3 dose escalation design has tested four doses of NBTXR3, equivalent to 5, 10, 15, and 22% of baseline theoretical tumor volume. The RP2D established as 22% of baseline tumor volume is further tested in the dose expansion part of the study. The primary endpoints of the dose expansion part are objective response rate (ORR) and complete response rate (CRR) of the primary tumor, by imaging according to RECIST v1.1. Safety is also evaluated.

Results: As of August 13, 2020, 43 patients have been treated in the dose expansion part of the study. The median age was 70.7 years old (range: 50.7- 89.9), 70% of patients had cardiac disorder risk, 44% had gastrointestinal disorder risk and 44% metabolic and nutrition disorder risk. The median tumor volume was 42.8 mL (range: 1.3 - 222.3). In the evaluable population for efficacy (N = 31), the ORR of the primary lesion was 83.9% and the CRR 67.7% at a median time of 7.8 months after NBTXR3 injection. Three patients (7%) experienced at least one serious adverse event (AE) related to the injection procedure and/or NBTXR3 which represented less than 1% of all reported AEs. RT-related toxicity was as expected with IMRT. Three deaths due to AEs related to RT and other causes were reported. The recruitment is ongoing and updated efficacy and safety results will be presented.

Conclusion: NBTXR3 intratumoral administration followed by IMRT may represent an option in elderly in elderly patients or patients with multiple comorbidities with LA-HNSCC who have limited therapeutic options. NBTXR3 activated by RT showed promising anti-tumor efficacy, supporting further evaluation in a phase III randomized trial.

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Head and Neck Cancer Patients Under (Chemo-) Radiotherapy Undergoing NUTritional Intervention: Results From the Prospective Randomized HEADNUT-Trial

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Purpose/Objective(s): Patients with squamous cell carcinoma of the head and neck (HNSCC) under (chemo-)radiotherapy are at high risk of malnutrition. There are no studies investigating the influence of nutritional status on an altered side effect spectrum and only very few studies examining bioelectric impedance analysis (BIA) and its impact as a prognostic indicator in patients with HNSCC undergoing (chemo-)radiotherapy. Our prospective, randomized, and controlled HEADNUT-trial presented here aimed at preventing increasing malnutrition under radiotherapy or concurrent chemoradiotherapy through specialized and individualized nutritional counseling. Additionally, we investigated whether parameters from BIA were suitable indicators for (threatening) malnutrition and inspected their prognostic effect on (clinical) outcome.

Materials/Methods: Between October 2018 and October 2020, 61 patients were randomized into an intervention and control group. Questionnaires (MUST, NRS-2002, and Nutriscore), clinical examinations, laboratory analyses, and BIA were used to assess nutritional status for all patients at the beginning and end of therapy as well as every 2 weeks during therapy. The intervention consisted of an individualized nutritional counseling every 2 weeks during therapy.

Results: Median baseline BMI for all participants was 23.8 (14.5-37.2) kg/m^2 and dropped to 22.9 (16.8-33) kg/m^2 after therapy ($P < 0.001$). In all patients, median baseline fat-free mass index (FFMI) was 18.1 (14-24.7) kg/m^2 and decreased to 17.8 (13.4-21.6) kg/m^2 till the end of therapy ($P < 0.001$). Compliant patients with a BMI < 22 kg/m^2 presented with less weight loss in the intervention group compared to the control ($P = 0.015$, CI: 0.33-2.95). At baseline, MUST was the only screening-test which