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Title

Exploratory Dosimetric Study of the Impact of the Pre-Radiation Therapy Intra Tumoral Injection of Hafnium Oxide Nanoparticles Along the Radiation Treatment of Extremity and Trunk Wall Soft Tissue Sarcomas

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Purpose/Objective(s): NBTXR3, injectable hafnium oxide nanoparticles, was designed to increase the energy deposit of the irradiation when activated by radiotherapy for the treatment of solid tumors. It is currently evaluated in a phase II/III clinical trial in soft tissue sarcoma (STS) [NCT02379845] of the extremity and trunk wall, to compare its efficacy when intratumorally injected and activated by radiotherapy versus radiotherapy alone. In this study, treatment planning depends on the Gross Tumor Volume (GTV) and dosimetric calculations, measured before injection of NBTXR3. A change in the GTV volume during radiotherapy treatment could impact the dosimetric coverage. In order to evaluate this change in GTV volume during radiotherapy treatment an ancillary study was put in place.

Materials/Methods: Among the 180 patients included in the STS phase II/III, 55 patients (pts) participated in this ancillary study in French sites. This study includes two treatment arms: (1) pts receiving an intratumor injection of NBTXR3 at a dose of 10% of the baseline tumor volume followed by RT (Intensity-modulated radiotherapy or 3D-RT) for 5 weeks for a total dose of 50 Gy; (2) patients receiving RT only with the same regimen. The treatment planning depends on the Gross Tumor Volume (GTV) and dosimetric calculations, measured before injection of NBTXR3. A change in the GTV volume during radiotherapy treatment could impact the dosimetric coverage. This evaluation consists in four CT-scan sessions planned as per protocol: before injection, after injection, and when reaching 30 Gy and 50 Gy dose of radiotherapy. Primary endpoint includes impact of NBTXR3 injection in the dosimetry coverage during radiotherapy; secondary endpoints include GTV variations after NBTXR3 injection and evaluation of clinical target volume (CTV) and planned target volume (PTV) during radiotherapy.

Results: 55 pts were included in this ancillary study. 25 received the NBTXR-3 injection, 30 did not. The GTV was contoured on the 4 CT scan realized per patient, injected or not, with corresponding value of CTV and PTV per protocol. The initial dosimetry was transferred on the new contours on each of these exams. The results of the variations of the GTV, CTV, PTV along the radiotherapy process, and the percentage covered by the initial 95% isodose recalculated on the 3 subsequent CT scan will be presented. The number of patient with a mean GTV dose as least equal to 90% of the prescribed dose (D95≥90%) will be calculated as the primary endpoint to assess the dosimetric impact of the injection.

Conclusion: NBTXR3 nanoparticles are activated by current standard radiotherapy without changing the applied dose and to increase the probability of interaction with incoming radiations to ameliorate the energy dose deposition from within tumor cells. The results of this study on the modifications of volumes during the radiotherapy treatment and their potential dosimetric impact will allow an objective evaluation of the dosimetric coverage all along the treatment period.

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