

Dipartimento Malattie oncologiche ed ematologiche  
Medicina nucleare UOC

Bologna, 28/6/2022

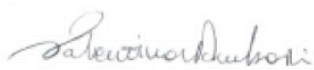
Response to EMA request (email IRCCS 7/6/2022)

Clinical trial: 151/2017/O/Sper; EudraCT2017-001307-68; Title "THE NOVEL 68Ga-PSMA THERANOSTIC PET/CT COMPOUND FOR FUNCTIONAL IMAGING OF GLIOMA" "IMPIEGO DELL'INNOVATIVO TRACCIANTE TERANOSTICO 68Ga-PSMA PER L'IMAGING FUNZIONALE PET/TC DEL GLIOMA"

The study enrollment was not started, as notified to the local EC. When the study was about to start, several publications (mentioned below) already demonstrated the potential diagnostic value of 68Ga-PSMA in glioma lesions and that PSMA uptake is evident in neovascularized lesions (and not in the normal brain tissue). These results already supported the correlation between 68Ga-PSMA uptake and pathology, especially in cases with suspected relapse, the most relevant clinical setting due to challenging image interpretation. This is also the setting in which PET/CT with amino-acid radiopharmaceuticals is already part of the diagnostic assessment. In view of these published results, the staging-presurgical setting (originally proposed to obtain direct correlation between histopathological data and PSMA-uptake, that was later demonstrated in the above-mentioned papers) seemed to have a marginal clinical impact. Furthermore, the intent of the study was to preferentially enroll outpatients but naïve patients with recent glioma-diagnosis turned out to often require in-hospital admission (in dedicated structures outside the enrollment hospital) due to fragile physical and psychological conditions. This issue resulted into difficult multidisciplinary management of patients and protocol.

Sincerely,

Valentina Ambrosini (PI) and Lucia Zannoni (coPI)



**PMID, Title, Authors, Citation, First Author, Journal/Book, Publication Year**

27846000, "Diagnostic Value of 68Ga PSMA-11 PET/CT Imaging of Brain Tumors-Preliminary Analysis", "Sasikumar A, Joy A, Pillai MR, Nanabala R, Anees K M, Jayaprakash PG, Madhavan J, Nair S.", "Clin Nucl Med. 2017 Jan

28737579, "Prostate-Specific Membrane Antigen-Targeted Imaging With [18F]DCFPyL in High-Grade Gliomas", "Salas Fragomeni RA, Menke JR, Holdhoff M, Ferrigno C, Laterra JJ, Solnes LB, Javadi MS, Szabo Z, Pomper MG, Rowe SP.", "Clin Nucl Med. 2017 Oct

29045711,"The endothelial prostate-specific membrane antigen is highly expressed in gliosarcoma and visualized by [68Ga]-PSMA-11 PET: a theranostic outlook for brain tumor patients?","Unterrainer M, Niyazi M, Ruf V, Bartenstein P, Albert NL.", "Neuro Oncol. 2017 Nov 29
29387926,"Glioblastoma multiforme: another potential application for (68)Ga-PSMA PET/CT as a guide for targeted therapy","Kunikowska J, Bartosz K, Leszek K.", "Eur J Nucl Med Mol Imaging. 2018 May
29731795,"Expression of Prostate-Specific Membrane Antigen (PSMA) in Brain Glioma and its Correlation with Tumor Grade","Saffar H, Noohi M, Tavangar SM, Saffar H, Azimi S.", "Iran J Pathol. 2018 Winter
29939953,"Utility of 68Ga-PSMA-11 PET/CT in Imaging of Glioma-A Pilot Study","Sasikumar A, Kashyap R, Joy A, Charan Patro K, Bhattacharya P, Reddy Pilaka VK, Oommen KE, Pillai MRA.", "Clin Nucl Med. 2018 Sep
30247210,"Uptake of Prostate-Specific Membrane Antigen-Targeted 18F-DCFPyL in Cerebral Radionecrosis: Implications for Diagnostic Imaging of High-Grade Gliomas","Salas Fragomeni RA, Pienta KJ, Pomper MG, Gorin MA, Rowe SP.", "Clin Nucl Med. 2018 Nov
30829867,"Differential Uptake of 68Ga-PSMA-HBED-CC (PSMA-11) in Low-Grade Versus High-Grade Gliomas in Treatment-Naive Patients","Verma P, Malhotra G, Goel A, Rakshit S, Chandak A, Chedda R, Banerjee S, Asopa RV.", "Clin Nucl Med. 2019 May