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POLICLINICO DI
SANT'ORSOLA

ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA

Dipartimento Malattie oncologiche ed ematologiche
Medicina nucleare UOC

Bologna, 28/6/2022

Response to EMA request (email IRCSS 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 hystopathological 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 Zanoni (coPI)

Valentina Ambrosini Lucia Zanoni

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

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