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“Theragnostics”

PET/CT features to predict survival outcome in GEP-NET patients treated with Lutathera: a multicentric machine learning radiomics study

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Tipologia di studio	Osservazionale, Clinico, Prospettico
Fase	-
N. soggetti	100
Razionale	<p>Radiomics can be defined as the extraction of quantitative characteristics ("features") from medical images to develop predictive, descriptive or prognostic models that may have clinical relevance [1, 2]. Even in consideration of the recent approval [3], nowadays no radiomics studies that evaluate the efficacy, the response and the statistical variations of features in GEP-NET patients treated with Lutathera are available. The proposed project would be the first study aimed at the development of a radiomics predictive model for GEP-NET patients treated with Lutathera and to assess the variations of the same features before and after Lutathera.</p> <ol style="list-style-type: none"> 1. Gillies RJ et al. Radiomics: Images Are More than Pictures, They Are Data. Radiology. 2016 2. Giesel FL et al. Correlation Between SUVmax and CT Radiomic Analysis Using Lymph Node Density in PET/CTBased Lymph Node Staging. J Nucl Med. 2017 3. FDA Approves Lutathera for GEP NET Therapy. J Nucl Med. 2018
Obiettivo	To identify from PET/CT images, the significant features for a predictive model of survival and response of GEP-NET patients treated with Lutathera. To evaluate the statistical variations (delta radiomics) and to correlate the significant features identified in the images before and after Lutathera, with outcome and response to Lutathera.

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Endpoint principale	To develop a predictive radiomics algorithm for survival and response of GEP-NET patients undergoing Lutathera treatment
Endpoints secondari	<p>To create an useful images database for further studies in terms of features validation-set and/or training of machine learning systems to medical decision support.</p> <p>Statistical analysis (delta radiomics) of the variations of the best features identified in the pre-Lutathera images respects to post-Lutathera images</p>
Popolazione dello studio	>/=100
Criteri di Inclusione e di esclusione	<p>Inclusion Criteria Patients with histopathological diagnosis of GEP-NET and eligible for therapy with Lutathera according to the inclusion criteria already recognized at the centres participating in the project. Availability of PET/CT images (68Ga-DOTA-peptides and possibly 18F-FDG) pre- and post-therapy of patients who will complete treatment with Lutathera (full cycles). Availability of clinical, laboratory and radiological data for a period of at least 12 months from the end of the PRRT treatment (follow-up).</p> <p>Exclusion Criteria Images of patients who did not complete the cycles of treatment. Removal of informed consent.</p>
Trattamento	Lutathera

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<p>Piano Statistico</p>	<p>From the analysis of the main radiomics studies in literature published in journals with the major IF in the Nuclear medicine and Oncology field, it appears that a cohort of patients not less than 100 is sufficient to reliably define the training and the validation set [4-6]. Sample-size calculation, considering a target population of n=100, indicated that at least 80 participants are needed (CI 95%; CL 5%). The cohorts of images to be subjected to training and validation will derive from the different centres involved, therefore the features will be preliminarily harmonized [7]. In this study the hypothesis is that only specific radiomics features are significant to predict survival and response of GEP-NET patients undergoing Lutathera treatment.</p> <p>4. Mayerhoefer ME et al. Radiomic features of glucose metabolism enable prediction of outcome in mantle cell lymphoma. Eur J Nucl Med Mol Imaging. 2019</p> <p>5. Elshafeey N et al. Multicenter study demonstrates radiomic features derived from magnetic resonance perfusion images identify pseudoprogression in glioblastoma. Nat Commun. 2019</p> <p>6. Wei W et al. A Computed Tomography-Based Radiomic Prognostic Marker of Advanced High-Grade Serous Ovarian Cancer Recurrence: A Multicenter Study. Front Oncol. 2019</p> <p>7. Orhac F et al. A Postreconstruction Harmonization method for Multicenter Radiomic Studies in PET. J Nucl Med. 2018</p>
<p>Nome del Centro Promotore e del PI dello studio</p>	<p>Department of Biomedical and Dental Sciences and of Morpho-Functional Imaging, Nuclear Medicine Unit, University of Messina, Via Consolare Valeria n.1, 98125 Messina, Italy.</p> <p>PI Prof Sergio Baldari</p> <p>Sub-PI Dr Riccardo Laudicella</p>
<p>Nome degli altri Centri partecipanti che hanno già aderito allo studio e dei relativi responsabili</p>	<p>Division of Nuclear Medicine, European Institute of Oncology Via Ripamonti 435 20141 Milano, Italy. Co-PI Dr Chiara Maria Grana</p> <p>Nuclear Medicine Unit, Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori (IRST) IRCCS, Via P. Maroncelli 40, 47014, Meldola, Italy. Co-PI Dr Federica Matteucci</p> <p>Fondazione IRCCS Istituto Nazionale Tumori Milano, ENETS Center of Excellence, Department of Medical Oncology, Milan, Italy. Co-PI Dr Ettore Seregni</p> <p>Nuclear Medicine Unit, Arcispedale Santa Maria Nuova IRCCS Reggio Emilia, Reggio Emilia, Italy. Co-PI Dr Angelina Filice</p> <p>Nuclear Medicine Unit, Diagnostic Imaging e Laboratory Medicine Department, University Hospital of Ferrara, Ferrara, Italy. Co-Pi Stefano Panareo</p>

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Data di inizio studio	01.01.2020
Data di fine studio	01.01.2023
Stato di avanzamento dello studio	Recruiting
Periodo di arruolamento in mesi	30 months
Data di inizio arruolamento	01.05.2019
Data di fine arruolamento	01.01.2022 (Because we need at least 12 months of FU data from the end of PRRT)
Data di approvazione Comitato Etico del Centro Promotore*	* In attesa di approvazione dello studio da parte del CE del Centro promotore