Titolo dello Studio

Somatostatin analogs as first line therapy in patients with advanced lung carcinoid: a multicenter Country-based analysis.

Informazioni di contatto del Centro promotore:	**Divisione di Oncologia Medica Gastrointestinale e Tumori Neuroendocrini** **Principal investigator: Francesca Spada, M.D., Ph.D.**
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Tipologia di studio	**Osservazionale □ Interventistico □** **Clinico □ Preclinico □** **Retrospettivo x Prospettico □**
Fase	**na x fase 2 x fase 3 □ fase 4 □**
N. soggetti	Unlimited
Razionale (max 100 parole)	The antitumor activity of somatostatin analogs (SSAs) was demonstrated in two pivotal prospective phase III trials, in advanced midgut NETs (PROMID) and EP (entero-pancreatic) and unknown primary NETs (CLARINET), but no randomized phase III trial has been performed so far in lung NETs. The only phase III trial specific for lung NETs has been prematurely stopped due to slow accrual (SPINET, NCT02683941). Evidence about a potential antitumor effect of SSAs in lung NETs comes from these above mentioned trials that have created the rationale to use SSAs also in non-functioning NETs of other origins and from few retrospective studies, often including mixed tumors population.

Obiettivo (max 50 parole)	The purpose of this retrospective observational study is to describe the use of long acting octreotide and lanreotide as first line therapy in patients with advanced lung NETs.
Endpoint principale (max 50 parole)	Progression free survival (PFS)
Endpoints secondari (max 100 parole)	Toxicity, overall survival
Popolazione dello studio (max 100 parole)	Clinical records of patients with diagnosis of lung NETs seen at participant centers from January 2008 to June 2018 will be reviewed.
Criteri di Inclusione e di esclusione (max 200 parole)	**Inclusion criteria:** 1) Histological diagnosis of typical or atypical carcinoid or not otherwise specified (NOS) carcinoid or well differentiated neuroendocrine tumor or low grade neuroendocrine tumor from lung; 2) Metastatic or unresectable locally advanced disease; 3) Therapy with long acting lanreotide or octreotide; 4) At least six months of long acting lanreotide or octreotide; **Exclusion criteria** 1) Poorly differentiated carcinoma from lung; 2) Extra-pulmonary NENs; 3) Prior systemic antitumor therapy.
Trattamento (max 50 parole)	Octreotide LAR or lanreotide autogel
Piano Statistico (max 200 parole) ***Includere la giustificazione per il clinical sample size ed il primary hypothesis testing***	Characteristics of patients will be presented using contingency tables and analyzed using standard descriptive statistics. Differences in the frequency of categorical variables between groups of patients will be assessed using the Fisher's Exact test, while difference of the distribution of continuous variables will be assessed using the Wilcoxon test or other non-parametric test. Survival analysis will be performed using the Kaplan-Meier methods and difference of survival between groups will be assessed using the log-rank test. Progression-free survival (PFS) will be evaluated by radiological follow up (CT or Ga68-PET-CT); Overall survival (OS) will be defined as the time from SSAs initiation to death from any cause; The safety of SSAs therapy (main adverse events) will also be evaluated and reported using descriptive statistics.

	All statistical analyses will be performed with the SAS software version 9.4 (Cary, NC). All tests will be two-sided and P<0.05 will be considered statistically significant.
Nome del Centro Promotore e del PI dello studio	**IEO, Milano, IRCCS** **Francesca Spada, M.D., Ph.D.**
Nome degli altri Centri partecipanti che hanno già aderito allo studio e dei relativi responsabili	**Brescia, Spedali Civili (Prof. A. Berruti) and all the available Italian centres involved in NEN management.**
Data di inizio studio	January 2020
Data di fine studio	June 2021
Stato di avanzamento dello studio (aggiornare annualmente)	
Periodo di arruolamento in mesi	6 months
Data di inizio arruolamento	January 2020
Data di fine arruolamento	June 2021
Data di approvazione Comitato Etico del Centro Promotore*	24/09/2019

* Allegare copia del documento attestante approvazione dello studio da parte del CE del Centro promotore, oppure autocertificazione da parte del PI dello studio attestante che l'approvazione del CE del proprio Ente non è richiesta per lo studio in oggetto.