

Titolo:	PROLoNg: Pembrolizumab and Radiotherapy for Oligometastatic squamous cell carcinoma of the head and Neck: a randomized phase III study
Patologia:	Testa-collo
Tipo di Studio:	Interventistico farmacologico
Fase:	3
Principali criteri di inclusione:	• Histologically confirmed squamous cell carcinoma of the head and neck of the oral cavity, oropharynx, hypopharynx, larynx or cervical primary occult and histologically or radiologically confirmed oligometastatic disease. Histological characterization of one metastatic lesion is strongly recommended. • Patients with synchronous or metachronous oligometastatic disease according to the ESTRO/EORTC consensus (1-5 metastatic lesions, with or without primary/recurrent primary tumour and/or regional disease c/rcN1-N3 present). • Amenable to first-line systemic treatment for R/M SCCHN. • HPV status using p16 IHC evaluated local for patients with oropharyngeal cancer. • PD-L1 CPS of at least 1 as evaluated locally. • Staging not older than 12 weeks before enrolment. • All the 1-5 metastases must be amenable to SABR. • Eligible for treatment with pembrolizumab.
Principali criteri di esclusione:	• Nasopharynx, sino-nasal, and salivary gland cancers are excluded. • In-field progression in < 6 months after curative intended locoregional irradiation of the head and neck. • Lesions larger than 6 cm in the largest dimension as measured in the diagnostic CT or MRI scan for lesions outside the brain. Note: bone metastases over 6 cm may be included if in the opinion of the local radiation oncologist they can be treated safely (e.g., rib, scapula, pelvis) and no inner organ is affected. • Brain metastases only. • Any prior radiotherapy to any of the 1-5 metastases that would be subject to SABR in the experimental arm unless the investigator agrees to treat only after discussion with the RTQA team.
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