



Groupe d'Etude des Tumeurs Endocrines

88 Rue de la Roquette, 75011 Paris

Tel : 06 14 61 04 76

Prevalence, characteristics and outcome of rare metastases of NET

Study Name	Prevalence, characteristics and outcome of rare metastases of NET
Clinical Study(ies)	National (French) Database of Neuroendocrine Tumors

<p>References regarding the clinical study (article, abstract...)</p>	<ol style="list-style-type: none"> 1. Thapa P et al. ¹⁷⁷Lu-DOTATATE Peptide Receptor Radionuclide Therapy in Metastatic or Advanced and Inoperable Primary Neuroendocrine Tumors of Rare Sites. World J Nucl Med. 2017 ;16(3):223-228 2. Carreras C et al., Rare metastases detected by (68)Ga-somatostatin receptor PET/CT in patients with neuroendocrine tumors. Recent Results Cancer Res. 2013;194:379-84 3. J. Calissendorff, A. Sundin, H. Falhammer, 68 Ga-DOTA-TOC-PET/CT detects heart metastases from ileal neuroendocrine tumors. Endocrine. 2014 Sep;47(1):169-76. 4. Makis W, McCann K, Bryanton M, McEwan AJ. Cardiac metastases of neuroendocrine tumors treated with ¹⁷⁷Lu DOTATATE peptide receptor radionuclide therapy or ¹³¹I-MIBG therapy. Clin Nucl Med. 2015 Dec;40(12):962-4. 5. Makis W, McCann K, McEwan AJ. Orbital Metastases of Neuroendocrine Tumors Treated With ¹⁷⁷Lu-DOTATATE PRRT or ¹³¹I-MIBG Therapies Clin Nucl Med. 2016 Feb;41(2):137-41.
<p>Investigators of the study</p>	<p>Lavinia Vija, Lawrence Dierickx, Rosine Guimbaud, Frederique Savagner, Frederic Courbon</p> <p><i>IUCT- Oncopole and CHU Toulouse</i></p>
<p>Study Objectives</p>	<ul style="list-style-type: none"> • The present study aims at exploring the patient and imaging characteristics of primary neuroendocrine tumors (NETs) of rare sites and rare metastatic localizations of NET who presented with metastatic and/or advanced inoperable stages and therefore was considered for peptide receptor radionuclide therapy (PRRT) with ¹⁷⁷Lu-DOTATATE. • To determine the prevalence and location of other sites of metastasis • To assess the correlation between the site of rare metastases and the primary neuroendocrine tumor site, NET staging; • To define the characteristics of response to

	<p>different therapies of rare sites of neuroendocrine tumors (treatment efficacy on somatostatin analogues; PRRT versus other systemic therapies)</p> <ul style="list-style-type: none"> • To look for eventual prognostic factors for response of these metastases to treatment • To look for the relevance of the metastatic spread and the survival and the prognostic of NET M1 patients • To identify those rare locations for which PRRT could be the treatment associated with the best clinical outcome
<p>Parameters to be analyzed</p>	<p><input type="checkbox"/> Available (already in the existing database)</p> <p><input checked="" type="checkbox"/> To be obtained (raw data are already available)</p> <ul style="list-style-type: none"> - Location of primary NET (rare primary location: eg: esophagus, mediastinum, breast) - Location of metastases (all locations, but especially other than liver, lymph nodes, bone: Such as: cardiac, thymus, retro-orbital, breast; genito-urinary, muscles, etc) <p>-number of PRRT cycles and type of radionuclide (Y-90, Lu-177)</p> <p>-assessment of response</p>
<p>Databases needed</p>	<p><input checked="" type="checkbox"/> Clinical Database</p> <p><input checked="" type="checkbox"/> AnaPath Database</p> <p style="padding-left: 40px;"><input type="checkbox"/> Available</p> <p style="padding-left: 40px;"><input type="checkbox"/> Not already available, Date of availability: ___/___/___</p> <p><input checked="" type="checkbox"/> Imagery Database</p> <p style="padding-left: 40px;"><input checked="" type="checkbox"/> Available</p> <p style="padding-left: 40px;"><input type="checkbox"/> Not already available, Date of availability: ___/___/___</p> <p><input checked="" type="checkbox"/> Other : _PFS, OS, censure_____</p> <p style="padding-left: 40px;"><input checked="" type="checkbox"/> Available</p> <p style="padding-left: 40px;"><input type="checkbox"/> Not already available, Date of availability: ___/___/___</p>

	<p>Database Supplier: _____</p> <p>Format of the Database : <input type="checkbox"/> SAS File <input checked="" type="checkbox"/> Excel file <input type="checkbox"/> ASCII <input type="checkbox"/> Other : _____</p> <p>Person in charge of the database transfer (statistician, other): _Romain Ricci _____</p>
<p>Aim of the analysis/study</p>	<p><input checked="" type="checkbox"/> Publication</p> <p><input checked="" type="checkbox"/> Congress If Congress, which one : <input checked="" type="checkbox"/> EANM <input type="checkbox"/> ASCO <input type="checkbox"/> ESE <input type="checkbox"/> Endocrine Society <input checked="" type="checkbox"/> GTE <input type="checkbox"/> Other : _____</p> <p><input checked="" type="checkbox"/> Exploratory aim</p> <p><input type="checkbox"/> Other : _____</p>
<p>Summary of the analyses</p>	<p><u>Population Sets:</u> -retrospective registration of patients with NET - description of primary NET characteristics and tumor metastases (synchronous / metachronous, location, number, treatment and response to treatment)</p> <p><u>Survival analysis:</u> in relation with PRRT vs other therapies</p>
<p>Comments</p>	<ul style="list-style-type: none"> • Database analysis and data collection of clinical and imaging information • To include following locations: <ul style="list-style-type: none"> - skin - retro-orbital (orbital muscles, etc) - intra-muscular - brain - thyroid

	<ul style="list-style-type: none"> - spleen - adrenals - testes - seminal vesicle - Other (breast, intracardiac, etc) <p>To exclude:</p> <ul style="list-style-type: none"> - ovary and uterus shall not be included as there is another project ongoing on this topic • The response shall be assessed post-PRRT by three parameters: <ul style="list-style-type: none"> 1.symptomatic response 2.biochemical response (serum tumor marker), 3.objective imaging response (RECIST, CT, liver MRI, reduction on the Krenning score ore number of uptake sites on somatostatin receptor imaging (Octreoscan®, Ga-DOTA-SSA PET/CT). • Retrospective analysis <ul style="list-style-type: none"> • Final aim: to identify the potential additional/ prognostic value of PRRT for treatment of specific rare metastases
Planned Date of presentation to the SC	07/SEPTEMBER/2018
Approbation by the CS	
Date of statistical report delivery	