

# EUROPE, AFRICA, AND MIDDLE EAST REGION



## Study Name

NELMAS: phase II study comparing adjuvant treatment with <sup>177</sup>Lu-DOTATATE (Lutathera®) to best supportive care in patients after resection of neuroendocrine liver metastases.

## Institution/Hospital

Imperial College London. London, UK.

## Principal Investigator

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## Description of Study

To compare overall 3-years Disease-Free Survival (DFS) after treatment with 2 cycles of <sup>177</sup>Lu-DOTATATE to best supportive care in patients with R0/R1 resected liver metastases of well differentiated (grade 1 or 2) gastro-entero-pancreatic neuroendocrine tumours and no extrahepatic disease manifestation prior to randomisation in the study.

## Inclusion Criteria

- Written informed consent prior to any study related procedures
- Patients aged 18 years or older
- ECOG / WHO performance status 0 or 1
- Patients with well differentiated grade 1 or grade 2 (Ki67<20%) GEP NET confirmed by histological criteria with the primary localisation in stomach, pancreas, or gut
- Patients after R0 (complete macroscopic and microscopic resection) or R1 (complete macroscopic resection, microscopically positive resection margins) resection of neuroendocrine liver metastases confirmed by histological criteria
- Patients with a primary tumour already resected or in whom the primary tumour has been resected synchronously with liver metastases
- MRI scan prior to surgery (within 4 -6 weeks) confirming liver metastases and no extrahepatic disease (except resectable perihilar lymph node involvement and/or primary tumour, if still in place)
- Somatostatin receptor-based imaging (<sup>68</sup>Ga DOTA-TATE PET/CT prior to surgery (within 12 weeks) confirming liver metastases and no extrahepatic disease (except resectable perihilar lymph node involvement and/or primary tumour, if still in place)

## Exclusion Criteria

- Less than 4 weeks post-surgery, or any other medical treatment, including chemotherapy, radiotherapy, and intrahepatic therapy
- High grade neuroendocrine tumours (G3 NET, or neuroendocrine carcinoma [NEC])
- After R2 (tumour debulking, macroscopically incomplete resection) resection of neuroendocrine liver metastases
- Patients with non-resectable neuroendocrine liver metastases and/or non-resectable primary tumour and /or non-resectable perihilar lymph node metastases
- Pregnancy
- Subjects of childbearing potential (both male and female participants) not willing to use a combination of adequate contraceptive measures, e.g., oral contraceptives, IUD, barrier methods of contraception (condom or occlusive cap with spermicide)
- Patients who have received prior systemic and/or liver-directed treatment for their metastatic NET other than somatostatin analogues
- Hb concentration <5.0 mmol/L (<8.0 g/dL)

- WBC <2x10<sup>9</sup>/L (2000/mm<sup>3</sup>)
- Platelets <75x10<sup>9</sup>/L (75x10<sup>3</sup>/mm<sup>3</sup>).
- Total bilirubin >3 x ULN.
- Serum albumin <3.0 g/dL unless prothrombin time is within the normal range.
- Uncontrolled congestive heart failure (NYHA II, III, IV).
- Uncontrolled diabetes mellitus as defined by a fasting blood glucose >2 ULN.
- Prior external beam radiation therapy to more than 25% of the bone marrow.
- Kidney failure with serum creatinine >150 µmol/L (>1.7 mg/dL)
- Known hypersensitivity to somatostatin analogues

Project Start Date

2023

Project End Date

2028

Open to other Sites Joining

Yes