Intra-arterial Hepatic (IAH) Infusion of Radiolabelled Somatostatin Analogs in GEP-NET Patients With Dominant Liver Metastases

NCT04837885

Status	RECRUITING
Phase	Phase 2
Sponsor	University Hospital, Bordeaux
Enrollment	23 participants

Plain Language Summary

This study is testing whether delivering radioactive therapy directly into the liver's blood supply — rather than through a vein — can improve outcomes for patients with a type of slow-growing gut or pancreatic tumor (called a neuroendocrine tumor) that has mainly spread to the liver.

You may be eligible if:
- You have a confirmed neuroendocrine tumor originating from the gut or pancreas
- Your disease has progressed despite standard treatment with a cold somatostatin analog
- You have already completed 4 standard cycles of LUTATHERA (a radioactive therapy)
- Most or all of your cancer is in the liver and cannot be surgically removed
- You have acceptable blood counts, kidney, and liver function
- You are 18 or older

You may NOT be eligible if:
- Your tumor showed a complete response (disappeared entirely) after LUTATHERA
- You have significant cancer outside the liver that threatens your life
- You have heart disease affecting your heart's pumping ability
- You have liver cirrhosis or other conditions preventing safe delivery of therapy into the liver's arteries
- You are pregnant or breastfeeding

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (11)

- Histologically proven well differentiated neuroendocrine tumor (NET) of gastrointestinal or pancreatic origin (GEP).
- Patients are progressive after treatment with cold somatostatin analog (within 12 months according to RECIST), or as soon as the diagnosis is made in case of hepatic invasion \> 50% without waiting for tumour progression
- Patient has received 4 standard of care LUTATHERA® cycles
- Liver Metastatic disease dominant or exclusive and assessable by RECIST 1.1, and not amenable to surgical resection after the last cycle
- ECOG performance status 0-2

... and 6 more (see full listing online)

Exclusion (13)

- Patients with complete response defined by the absence of lesion according to RECIST 1.1 realized during morphological imaging at inclusion (chest-abdomen-pelvis CT scan and hepatic MRI)
- No residual uptake according to standard 177-Lu scintigraphy performed in the clinical routine 24 hours after each LUTATHERA IV treatment
- Carcinoid heart disease (LVEF \< 40%)

• Dominant or threatening extrahepatic metastases or that may affect vital prognosis

• Contraindications to intra-hepatic arterial infusion (coagulation disorders, portal thrombosis, intra-hepatic biliary tract dilatation, digestive or biliary anastomosis or fistula, cirrhosis (Child Pugh B8 or C…)

... and 8 more (see full listing online)

Locations (4 total)

Institut Bergonié, Bordeaux, France
Institut de cancérologie du Gard (ICG) - CHU de Nîmes, Nîmes, France
CHU Bordeaux - Hôpital Haut Lévêque, Pessac, France
... and 1 more locations