Combined Beta- Plus Auger Electron Therapy Using a Novel Somatostatin Receptor Subtype 2 Antagonist Labelled With Terbium-161 (161Tb-DOTA-LM3)

NCT05359146

Status	RECRUITING
Phase	Early Phase 1
Sponsor	University Hospital, Basel, Switzerland
Enrollment	16 participants

Plain Language Summary

This study is testing a new type of radiation therapy using a radioactive substance called terbium-161 attached to a molecule that targets tumor cells in people with neuroendocrine tumors (NETs) of the gut and pancreas that have spread to other parts of the body.

You may be eligible if...
- You have been diagnosed with a metastatic neuroendocrine tumor of the gut or pancreas (grade 1 or 2)
- Surgery to remove your cancer is not a curative option
- You have at least 2 measurable tumors on imaging
- A special PET scan has confirmed your tumors have the receptor this therapy targets (SST2)
- You are over 18 years old
- If you can become pregnant, you are using reliable contraception

You may NOT be eligible if...
- You are pregnant or breastfeeding
- Your tumors are not visible on the required PET scan
- You have poor kidney or bone marrow function
- You have received too many prior lines of similar radiation therapy

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

Key Eligibility Criteria

Inclusion (11)

- Written consent
- Patients with diagnosed and metastasized secreting and non-secreting GEP-NEN (grade 1 and 2)
- Absence of a curative surgical option
- At least 2 measurable tumours based on RECIST 1.1 (minimal tumour diameter of 1 cm)
- Documentation of a positive 68Ga-DOTATOC/-TATE positron emission tomography (PET)/CT (in vivo detection of SST2 on GEP-NENs)

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

Exclusion (9)

- Known intolerance against 177Lu, 161Tb, DOTA, TOC, LM3, SST analogues or against one of the components of 177Lu-DOTA-TOC or 161Tb-DOTA-LM3
- Bone/bone marrow metastases located in the lumbar spine if they affect the bone marrow dose estimation
- Ongoing infection at the screening visit or a serious infection in the past 4 weeks
- Administration of another investigational product in the last 60 days before Visit 1 Day 1

• Prior or planed administration of a therapeutic radio-pharmaceutical during 8 half-lives of the used radio-pharmaceutical's radionuclide, also during the ongoing study

... and 4 more (see full listing online)

Locations (1 total)

Division of Nuclear Medicine, University Hospital Basel, Basel, Switzerland