# *KURZPROTOKOLL*
# *Compete*

| | |
|---|---|
| **Öffentlicher Titel** | Phase III Studie zur Peptid-Rezeptor-Radionuklid-Therapie mit 177Lu-edotreotide bei gastroentrologischen oder pankreatischen neuroendokrinen Tumoren |
| **Wissenschaftl. Titel** | A prospective, randomised, controlled, open label, multicentre phase III study to evaluate efficacy and safety of Peptide Receptor Radionuclide Therapy (PRRT) with 177Lu Edotreotide compared to targeted molecular therapy with Everolimus in patients with inoperable, progressive, somatostatinreceptor positive (SSTR+), neuroendocrine tumours of gastroenteric or pancreatic origin (GEP-NET) |
| **Kurztitel** | Compete |
| **Studienart** | multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie |
| **Studienphase** | Phase III |
| **Erkrankung** | Drüsen/Hormone/Stoffwechsel: Neuroendokrine Tumoren |
| **Einschlusskriterien** | - Histologically and clinically confirmed diagnosis of well-differentiated neuro-endocrine tumour of non-functional gastroenteric origin (GE-NET) or both functional or non-functional pancreatic origin (P-NET)<br>- Measurable disease per RECIST 1.1<br>- Somatostatin receptor positive (SSTR+) disease<br>- Radiological disease progression, defined as progressive disease per RECIST 1.1. criteria |
| **Ausschlusskriterien** | - Known hypersensitivity to edotreotide or everolimus<br>- Known hypersensitivity to DOTA, lutetium-177, or any excipient of edotreotide or everolimus or any other Rapamycin derivative<br>- Prior exposure to any peptide receptor radionuclide therapy (PRRT)<br>- Prior therapy with mTor inhibitors<br>- Prior EFR (external field radiation) to GEP-NET lesions or radioembolisation therapy<br>- Therapy with an investigational compound and/or medical device within 30 days prior to randomisation<br>- Indication for surgical lesion removal with curative potential<br>- Planned alternative therapy (for the period of study participation)<br>- Serious non-malignant disease<br>- Renal, hepatic, cardiovascular, or haematological organ dysfunction, potentially interfering with the safety of the study treatments<br>- Pregnant or breast-feeding women<br>- Subjects not able to declare meaningful informed consent on their own (e.g. with legal guardian for mental disorders) or any other vulnerable population to that sense (e.g. persons institutionalised, incarcerated etc.) |
| **Alter** | 18 Jahre und älter |
| **Molekularer Marker** | SSTR |
| **Prüfzentren** | **Universitätsklinikum Gießen und Marburg, Standort Marburg** (Rekrutierung beendet)<br>Baldingerstraße<br>35043 Marburg<br>Mariana May<br>Tel: 06421 58 67022<br>mariana.may@uk-gm.de |
| **Sponsor** | ITM Solucin GmbH |
| **Registrierung in anderen Studienregistern** | EudraCT 2016-001897-13<br>ClinicalTrials.gov NCT03049189 (primäres Register) |