Press Release

Phase 2 study interim report presented at the Annual Congress of the German Society of Nuclear Medicine

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The CSO of TRIMT GmbH, PD Dr. Johannes Notni, will present the interim report of a phase 2 study evaluating the diagnostic performance of the avb6 integrin-targeting PET tracer ^{68}Ga-Trivehexin at the annual congress of the German Society of Nuclear Medicine (DGN) in Leipzig on April 12, 2024.

The investigator-initiated trial is being conducted at the Department of Nuclear Medicine and Molecular Imaging of Fortis Memorial Research Institute in Gurugram (India) under the direction of Dr. Ishita B. Sen (Director&Head of Department). Together with nuclear medicine experts Dr. Subho Das, Dr. Dharmender Malik and Dr. Parul Thakral, the study is aiming at investigating the correlation between ^{68}Ga-Trivehexin uptake and $\alpha v\beta 6$ integrin expression in HNSCC and PDAC patients.

Background:
[68]Ga-Trivehexin [1] is a highly affine (IC_{50}=47 pmol) and selective PET tracer for $\alpha v\beta 6$-integrin, which is strongly upregulated in many carcinomas, such as pancreatic ductal adenocarcinoma (PDAC) and head and neck squamous cell carcinoma (HNSCC). This ongoing clinical Phase 2 study aims at correlation of ^{68}Ga-Trivehexin tumor uptake and $\alpha v\beta 6$-integrin expression determined by immunohistochemistry (IHC).

Methods:
[68]Ga-Trivehexin was synthesized via an established in-house kit-like protocol [2]. 33 patients (age 19-76 y; 24 m, 9 f), thereof 20 with suspected HNSCC and 13 with suspected PDAC, underwent ^{68}Ga-Trivehexin as well as [18F]FDG PET/CT on separate days. Tissue biopsies of the suspected primary/ metastatic tumor site were obtained from 29 patients. $\alpha v\beta 6$-integrin expression in specimen was analyzed by IHC, and categorized by an experienced pathologist using the immune-reactive score (IRS) and modified 4-point IRS classification.

Results:
[68]Ga-Trivehexin PET/CT showed good tracer uptake in 24/29 patients. Histology of 29 biopsies revealed 9 PDACs, 1 pancreatic neuroendocrine tumor, 1 adenocarcinoma colon, 15 HNSCC, 2 benign inflammatory changes, and 1 inconclusive result. The 24 patients with PDACs and HNSCC showed good ^{68}Ga-Trivehexin uptake in primaries and metastases (mean SUVmax 6.04 ± 3.8), with a better tumor to background ratio in comparison to ^{18}F-FDG PET/CT. ^{68}Ga-Trivehexin SUVmax showed a strong locoregional correlation with IRS scores (r=0.61; P=0.002), while there was no such correlation observed with [18F]FDG PET (r= 0.38; P=0.066). A higher $\alpha v\beta 6$-integrin expression was seen at the tumor margins than in the center, concordant with the observed pattern of ^{68}Ga-Trivehexin uptake.

Discussion:
To our knowledge, this is the first in-human study that correlates $\alpha v\beta 6$-integrin IHC in various carcinomas with ^{68}Ga-Trivehexin uptake. As of now, this study shows that ^{68}Ga-Trivehexin allows for a good quantitative assessment of tumoral $\alpha v\beta 6$-integrin expression by PET imaging.

References:
[1] Quigley NG, Steiger K, Hoberück S, Czech N, Zierke MA, Kossatz S, Pretze M, Richter F, Weichert W, Pox C, Kotzerke J, Notni J. PET/CT imaging of head-and-neck and pancreatic cancer in humans by targeting the "Cancer Integrin" $\alpha v\beta 6$ with Ga-68-Trivehexin. Eur J Nucl Med Mol Imaging. 2022; 49:1136-1147. doi: 10.1007/s00259-021-05559-x.

[2] Thakral P, Das SS, Dhiman S, Manda D, Virupakshappa CB, Malik D, Sen I. Validation of In-House Kit-Like Synthesis of 68Ga-Trivehexin and Its Biodistribution for Targeting the Integrin $\alpha v\beta 6$ Expressing Tumors. Cancer Biother Radiopharm. 2023; 38:468-474. doi: 10.1089/cbr.2022.0080.

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