Conclusion: Despite a number of hurdles, the CMRF reactions are currently being widely employed for the production of radiopharmaceuticals embodying a wide variety of ^{18}F-aryl scaffolds. To overcome the purification difficulties of fluorine-18-containing radioligands due to H-side product formation, further improvements and mechanistic studies need to be undertaken.

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PP02

Radionuclidic purity of ^{68}Ga eluted from ^{68}Ge/^{68}Ga generators by Thin Layer Chromatography

Tania P B Tchobnian[1], Joao A Osso Jr[2*]
[1]IPEN-CNEN/SP, Brazil. [2]Retired, independent consultant, Brazil
[*]**Corresponding author**: jaossoj@yahoo.com.br

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Background: ^{68}Ga is a PET emitter radionuclide with an important role in nuclear medicine diagnosis procedures. The physical half-life of 68 min is compatible with the pharmacokinetics of many biomolecules and low molecular weight substrates. Another important feature is its availability from a generator system, where the parent radionuclide, ^{68}Ge ($t_{1/2} = 270.95$ days) is adsorbed on a column and daughter, ^{68}Ga, is eluted in ionic form $^{68}Ga^{3+}$. The objective of this work was to develop a new method for the determination of the radionuclidic purity [1] of ^{68}Ga, allowing a fast determination of the ^{68}Ge breakthrough in ^{68}Ga eluates.

Materials and methods: The method to evaluate the ^{68}Ge impurity in ^{68}Ga samples recommended by the European Pharmacopeia is to measure the activity of 68Ga eluted from the generator, allow 24 h decay and measure the same sample. All ^{68}Ga activity will come from the decay of ^{68}Ge, so the level of ^{68}Ge is calculated. The proposed methodology was based on the different behaviour of Ge and Ga in thin layer/paper chromatography [2]. Several solvents and strips were tested, as well as different solutions added to the spot point to interact with the species. The detection and quantification limits were calculated for the best system to evaluate the possibility of reaching the maximum level of ^{68}Ge given in the monograph.

Results: The best system was achieved using TLC-SG-IB-F strips, acetone as solvent and a solution of 3 mol L^{-1} HCl added to the spot point of the strip. The retention factors were 0.1 for ^{68}Ge and 0.5-0.6 for ^{68}Ga, allowing to cut the strips into 2 pieces for measuring in the detector. The detection and quantification limits showed that the strip sample could be measured 2 h after the beginning of the quality control procedure, then correcting to the full growth of ^{68}Ge. Samples were measured using the traditional and the proposed method and the values were similar.

Conclusions: The proposed method is simple, fast and allow the evaluation of the ^{68}Ge impurity in samples of ^{68}Ga freshly eluted from the generators.

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PP03

TECANT Journey: Tracing the Path of ^{99m}Tc-labelled Somatostatin Antagonist from Concept to Clinical Realization

Renata Mikolajczak[1], Irene Virgolini[2], Luka Lezaic[3], Gianpaolo di Santo[2], Clemens Decristoforo[2], Petra Kolenc[3], Marta Opalinska[4], Andrej Studen[5], Piotr Garnuszek[1], Urban Simoncic[5], Malgorzata Trofimiuk-Muldner[4], Christine Rangger[2], Boguslaw Glowa[6], Konrad Skorkiewicz[6], Melpomeni Fani[7], Anna Sowa Staszczak[4], Barbara Janota[1], Marko Kroselj[3], Sebastijan Rep[3], Anton A. Hoermann[2], Alicja Hubalewska-Dydejczyk[4]
[1]National Centre for Nuclear Research Radioisotope Centre POLATOM, Otwock-Swierk, Poland. [2]Department of Nuclear Medicine, Medical University Innsbruck, Innsbruck, Austria, [3]Department of Nuclear Medicine, University Medical Centre Ljubljana, Ljubljana, Slovenia. [4]Chair and Department of Endocrinology, Jagiellonian Medical College, Krakow, Poland. [5]Faculty of Mathematics and Physics, University of Ljubljana, Ljubljana, Slovenia. [6]University Hospital Krakow, Kraków, Poland, 7Universitätsspital Basel, Basel, Switzerland.

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Aim: Radiolabelled somatostatin analogues targeting tumors overexpressing somatostatin receptors (SST) are powerful tools in managing patients with neuroendocrine neoplasms (NENs). Although SST agonists, labelled with technetium-99m or gallium-68, are currently established diagnostic tools for imaging NENs, there is an extensive ongoing development of radiolabelled SST antagonists. The advantages of ^{68}Ga-labelled SST antagonists have been recently demonstrated (1). Quantitative imaging with single-photon emitting ^{99m}Tc-labelled SST antagonists can be widely available and might represent a significant advancement in the management of NEN patients.

Here we describe the preclinical and pharmaceutical development of the SST antagonist [^{99m}Tc]Tc-TECANT1 and the first results of the feasibility clinical study.

Materials and methods: Two compounds (N4-LM3 and N4-p-Cl-BASS) were successfully radiolabelled with technetium-99m and compared with in vitro and in vivo tests (2). The kit formulation with N4-LM3: p-Cl-Phe-cyclo(D-Cys-Tyr-DAph(Cbm)-Lys-Thr-Cys)-D-Tyr-NH2 (TECANT1) was developed and manufactured in compliance with cGMP requirements (3).

Ten patients with advanced NEN and confirmed SST positivity were enrolled in the phase I multicenter clinical study (EudraCT No: 2019-0033779-20) assessing the safety, tolerability, pharmacokinetics, dosimetry, and NEN targeting properties of [^{99m}Tc]Tc-TECANT1.

Results: Based on extensive preclinical studies the most promising SST antagonist TECANT1 was selected for clinical translation as an investigational medicinal product (IMP). The final composition of the freeze-dried 3-vial kit was established. The kit formulation was successfully adapted for three GMP grade batches that met all predefined specifications, based on several Ph. Eur. monographs and guidelines. These include those for the kit itself and those related to the radiolabelled product.

The subsequent clinical feasibility study confirmed the safety of [^{99m}Tc]Tc-TECANT1. [^{99m}Tc]Tc-TECANT1 showed a rapid distribution with predominant renal excretion and a very high detection rate in all examined patients. In most cases a higher contrast was achieved with [^{99m}Tc]Tc-TECANT1 in comparison to ^{68}Ga-SST agonists, the current gold standard in NENs imaging.

Conclusion: Within the TECANT project (ERA-PER med), the ^{99m}Tc-labelled SST antagonist TECANT1 was selected for clinical translation based on its favorable preclinical data. The 3-vial kit formulation was successfully translated into the clinical setting.

We consider that the [^{99m}Tc]Tc-TECANT1 development may be the key to a reliable assessment of the SST status (primary focus/metastasis) and will be important for improving personalized NEN management. The final results of the clinical study are pending.

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