Scandium-44 purification and its preparation towards FAP-targeted radiopharmaceuticals

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FACTS & FIGURES

Start date:	01/10/2024
End date:	30/09/2029
Grant agreement number:	101172788 (IHI- Call 5)
Contributions:	
EU funding	14 130 974 €
Industry contribution	7 550 500 €
Contributing partners	4 197 618 €
Project website:	https://www.thera4care.eu
Social media:	LinkedIn

CHALLENGE

THERA4CARE'S OBJECTIVE

- Advancement of **personalized cancer treatments** through radiotheranostics
- Translation of innovative **radiotheranostic research into clinical practice**
- Establishment of a **reliable European supply chain** for critical radiotheranostics resources

Innovative radiotheranostic research ⇢ Clinical practice

OUR RESEARCH FOCUS

Clinical translation of ^{44}Sc-FAPI compounds for PET imaging



APPROACH & METHODOLOGY

1) Optimization of scandium-44 purification (WP4)

Enhancement of product purity and activity concentration

2) Identification of the optimal ^{44}Sc-FAP ligand (*e.g. FAPI-46; OncoFAP; FAP-2286; 3BP-3940*) and preclinical evaluation (WP3 & WP4)

in collaboration with the Nuclide Chemistry Group at PSI

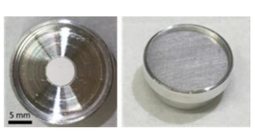
Identification of the most promising candidate

3) Development of an automated radiolabelling synthesis towards ^{44}Sc-FAPI radiopharmaceutical manufacture

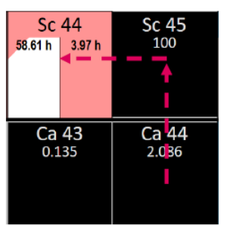
Ensure robust and reproducible production of a patient dose
Enable clinical translation and support future clinical trials

RESULTS

TARGET IRRADIATION



^{44}CaO target
20 mg
6 mm × 0.5 mm



^{44}Ca(p,n)^{44}Sc
σ_{max} = 600 mbarn at 10.3 MeV, 50µA, 60min

Up to 5.5 GBq produced @ EOB

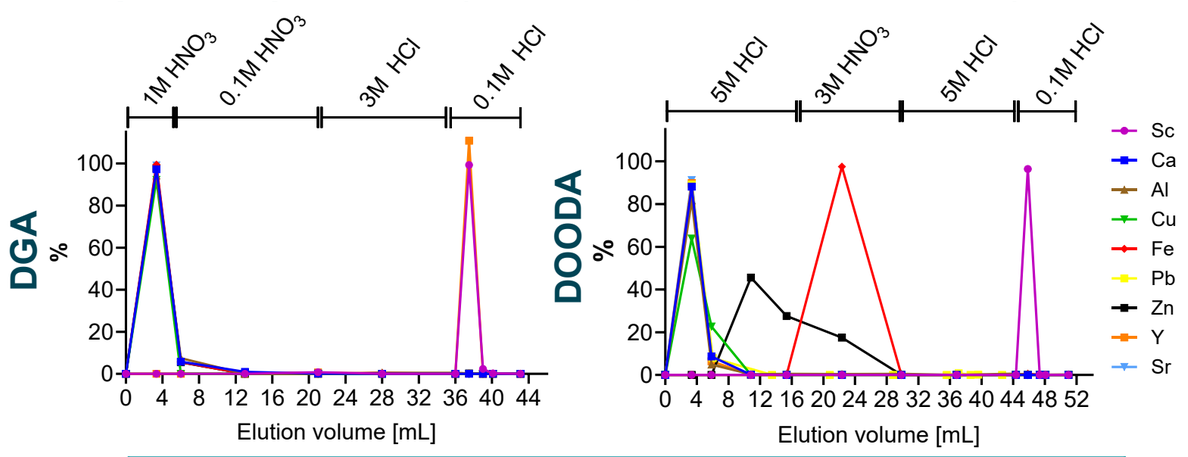
^{44}Sc separation from target material and impurities



RESULTS

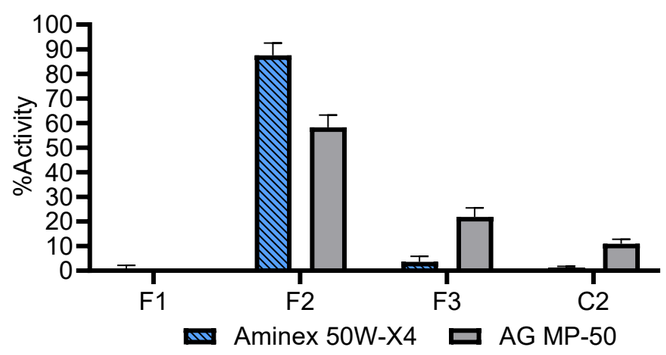
RADIOCHEMISTRY

Separation procedure (Column 1, EXTRACTION RESIN)



	DGA (established)	DOODA (new)
Column height	10 mm	10 mm
Eluted volume	4 mL	4 mL
Final Sc recovery (inactive experiments)	≥96% (n=3)	≥95% (n=3)
Yield (radioactive experiments)	92±3% (n=18)	94±2% (n=4)

Final elution optimization (Column 2, CATION EXCHANGE RESIN)



	AG MP-50 (established)	Aminex 50W-X4 (new)
Column height	3 mm	3 mm
Total eluted volume	1500 µL	1500 µL
Yield (3 fractions,1500µL)	80±3% (n=8)	92±3% (n=14)
Yield (F2, 500µL)	58±5% (n=8)	87±5% (n=14)
Activity concentration in F2	≤4.9GBq/mL	≤7.7GBq/mL

QUALITY CONTROL

Radionuclidic purity (γ-spectrometry)

DGA : RNP>98.8% ; Y-88 impurity* <0.0005%
DOODA : RNP>98.8% ; Y-88 impurity* ND
**from Sr-88 in target material, γ-spectrometry one month after EOB*

Radiolabelling efficiency with DOTATOC
≤60 MBq/nmol, RCP≥95%

Chemical purity (ICP-MS)
For both separation procedures:
Fe, Zn < 10 µg/GBq; as for ^{68}Ga Ph.Eur.
Pb, Cu< 1 µg/GBq as for ^{177}Lu Ph.Eur.

VALUE OF IHI COLLABORATION

- Clinical translation is pursued through automated synthesis, in **collaboration with PSI's Clinical Drug Supply group, clinicians, and potential industrial partners**

Bridging research and clinical application

CAREER IMPACT

- Gain experience in **GMP-compliant radionuclide production** and adapt research to **industrial requirements**
- Develop **translational and multidisciplinary skills** across the radiopharmaceutical workflow while **expanding the professional network**

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