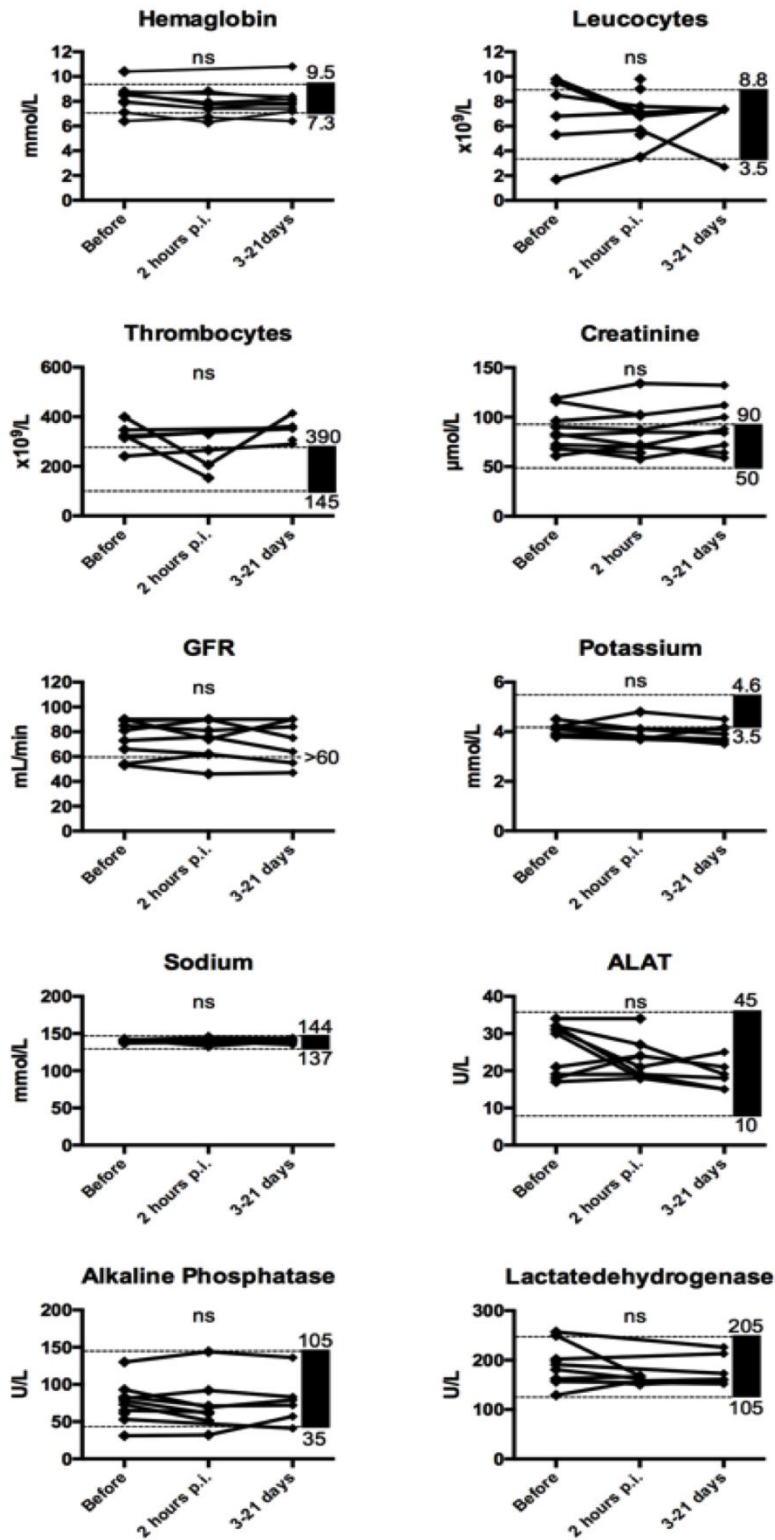


Supplemental Figure 1. Specifications and results of the ^{68}Ga -NOTA-AE105 preparations.



Supplemental Figure 2. Blood pressure and heart rate following injection of ^{68}Ga -NOTA-AE105

Supplemental Table 1

Analysis	Specification	Results (n=10)
Appearance	Clear and colorless	Clear and colorless
Radioactivity	100 – 500 MBq	423 MBq \pm 37 MBq
Radiochemical purity ⁶⁸ Ga-NOTA-AE105 (HPLC)	\geq 91% (combined)	97.0 % \pm 1.3 %
⁶⁸ Ga ³⁺ and ⁶⁸ Ga-colloid (TLC)	\geq 91% \leq 2 %	97.2 % \pm 1.2 % 0.18 % \pm 0.18 %
Chemical purity Ethanol Acetone Metal-NOTA- AE105	\leq 8 % < 5000 ppm Max. injected dose: 40 ug	6.4 % \pm 1.1 % 14 ppm \pm 8 ppm 33.2 μ g \pm 7.6 μ g
pH	4.0 – 8.0	7.1 \pm 0.9
LAL-test	0.125 IU/ml	All < 0.125 IU/ml
Sterility test	Sterile	All sterile*
Shelf-life	2 hours	2 hours

The specifications for radiochemical purity and ethanol are similar to the specifications in the ⁶⁸Ga-DOTATOC monograph. The specification for acetone is based on the limits defined in "ICH guideline Q3C (R5) on impurities: guideline for residual solvents".

A dose of 40 μ g is considered safe based on our toxicology studies.

Pyrogen testing was performed on all productions for patient studies. The results were obtained post release.

*The sterility of 3 validation batches was tested. The results were obtained before the study was initiated.

Supplemental Table 1. Blood biochemistry parameters in each patient. Individual plots of hemoglobin, leucocytes, thrombocytes, creatinine, estimated glomerular filtration rate (eGFR), potassium, sodium, alanine aminotransferase (ALAT), alkaline phosphatase and lactate-dehydrogenase before injection of ⁶⁸Ga-NOTA-AE105, immediately after and on return to the hospital 3-21 days following the study day. No significant differences in any parameter were found. Black bars in the right side of the figure with top-bottom values indicate reference interval.

Blood pressure and Pulse during the PET/CT scans															
Time	Before			1 min post injection			10 min post injection			1 hour post injection			2 hours post injection		
Patient #	Systolic	Diastolic	Pulse	Systolic	Diastolic	Pulse	Systolic	Diastolic	Pulse	Systolic	Diastolic	Pulse	Systolic	Diastolic	Pulse
1	121	70	69	105	71	60	103	67	77	117	75	64	118	66	72
2	159	98	98	158	104	93	171	99	89	161	96	88	155	93	90
3	147	71	58	143	66	57	146	71	57	169	72	61	177	74	67
4	138	83	68	153	100	73	150	101	69	137	88	71	150	92	73
5	119	73	64	125	74	69	101	63	69	113	66	68	110	73	68
6	134	74	69	104	61	65	103	54	69	125	76	89	128	75	73
7	127	73	80	120	69	79	120	82	82	144	79	83	137	80	92
8	124	75	75	114	75	75	121	74	72	130	81	69	128	83	68
9	150	103	80	144	93	76	141	91	78	146	97	74	138	88	80
10	177	93	68	169	96	68	147	91	61	155	97	64	146	81	61

Supplemental Table 2. Metabolic analysis of ⁶⁸Ga-NOTA-AE105 in plasma. Relative time-dependent activity concentrations in plasma (n=6). Plasma half life was estimated to 8.5 min.