

Safety profile results

In relation to the safety profile, no significant changes were observed in the vital parameters recorded at 4 hours, 24 hours and 10 days compared to baseline and no clinical signs or symptoms of any kind were observed for the entire monitoring period.

In relation to the laboratory parameters, no clinically significant changes in the laboratory parameters were recorded nor any kind of toxicity according to the NCI CTAE classification vers. 4.03 and in particular no liver toxicity signs were recorded.

No adverse events of any kind were observed in any patient.

Events in the total number of participants (50)	Number of AE	%
Serious AE	0	0
IMP related AE	0	0
AE occurred within 24h after IMP administration	0	0
AE causing trial interruption	0	0
AE leading to a corrective or preventive action	0	0
AE alteration of laboratory parameters	0	0
Death	0	0
Total number of AE	0	0

Dosimetric results

The actual calculated doses are such that there is no toxicity due to the diagnostic administration. The doses absorbed by the organs per unit of activity administered and effective dose per unit of activity administered calculated according to the ICRP methodology 103 are illustrated in the following table.

Table 1: Doses absorbed by the organs per unit of activity administered and effective dose per unit of activity administered calculated according to the ICRP methodology 103.

Absorbed dose for unit of administered activity (mGy/MBq)	Mean	±	standard deviation
Adrenals	4.40E-02	±	9.90E-03
Brain	1.50E-02	±	3.30E-03
Breasts	2.00E-02	±	1.40E-03
Gallbladder Wall	7.20E-02	±	2.30E-02

LLI Wall	2.20E-02	±	2.80E-03
Small Intestine	1.90E-01	±	1.20E-01
Stomach Wall	2.80E-02	±	3.30E-03
ULI Wall	4.00E-02	±	1.10E-02
Heart Wall	3.20E-02	±	3.80E-03
Kidneys	9.40E-02	±	2.10E-02
Liver	6.40E-01	±	2.80E-01
Lungs	7.30E-02	±	4.10E-02
Muscle	1.30E-02	±	3.70E-03
Pancreas	4.10E-02	±	8.20E-03
Red Marrow	2.20E-02	±	2.20E-03
Osteogenic Cells	3.50E-02	±	4.50E-03
Skin	1.60E-02	±	1.50E-03
Spleen	2.20E-02	±	1.70E-03
Testes	1.50E-02	±	2.80E-03
Thymus	2.00E-02	±	1.60E-03
Thyroid	1.60E-02	±	2.70E-03
Urinary Bladder Wall	1.90E-02	±	2.30E-03
Effective dose ICRP 103 (mSv/MBq)	6.00E-02	±	1.60E-02

