

Intracerebral Implantation of Human Neural Stem Cells and Motor Recovery after Stroke: Multi-centre Prospective Single-Arm Study (PISCES-2)

Supplementary Data

Supplementary Table 1: Study Schedule

	Pre Surgery			Post Surgery							
	Visit 1	Visit 2	Visit 3	Visit 4	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10
Visit window	Day 28 - (270 ±7) post stroke	Visit 1 + 28 days to day 300 (±7) post stroke	Up to 7 days prior to surgery	Day 0 within 3m of visit 2	Day 0-2 (First 48h post injection	Day 2	Day 7 (±2)	Day 28 (±4)	Day 90 (±7)	Day 180 (±14)	Day 365 (±30)

Supplementary Table 2: Responses rates subdivided by baseline NIHSS upper limb motor score.

Supplementary Table 2: Responders to Primary and Secondary Endpoints.

Response	ARAT subtest 2 (grasp) Primary Outcome		ARAT Total Response		Modified Rankin Scale		Barthel Index*		One or More	
	≥2 point improvement	4	≥6 point improvement	4	≥ 1 category improvement	4	≥ 9 point improvement	4	2 or 3	4
NIHSS UL Motor score	2 or 3	4	2 or 3	4	2 or 3	4	2 or 3	4	2 or 3	4
3 months	1/14 (7%)	0/9 (0%)	3/14 (21%)	0/9 (0%)	6/14 (43%)	1/9 (11%)	3/14 (21%)	5/9 (56%)	8/14 (57%)	5/9 (55%)
6 months	3/13 (23%)	0/9 (0%)	4/13 (31%)	0/9 (0%)	5/13 (39%)	1/9 (11%)	4/14 (31%)	3/9 (33%)	9/13 (69%)	4/9 (44%)
12 months	3/12 (25%)	0/8 (0%)	5/12 (42%)	0/8 (0%)	6/12 (50%)	1/8 (13%)	3/12 (25%)	5/8 (63%)	9/12 (75%)	5/8 (62%)

Supplementary Table 3: Individual patient data for all functional measures.

Subject No	NIHSS Total	NIHSS Arm Motor	ARAT Item 2				ARAT Total Score				Barthel Index				Modified Rankin Scale			
	Baseline	Baseline	Baseline	d90	d180	d365	baseline	d90	d180	d365	Baseline	d90	d180	d365	Baseline	d90	d180	d365
1	6	2	0	1	2	3	0	22	38	54	95	95	100	100	3	2	3	2
2	5	2	0	0	0	0	3	3	3	3	80	75	75	85	3	3	3	3
3	4	2	1	3	3	3	7	43	51	57	95	100	100	100	3	2	2	2
4	3	2	0	0	0	0	7	7	8	7	85	85	90	75	3	3	3	3
5	4	2	0	0	0	0	3	4	6	6	100	100	100	100	2	1	1	1
6	3	2	0	1	1	0	0	9	9	9	90	95	100	85	3	2	2	2
7	8	2	0	0			0	0			95	90			3	3		
8	6	2	0	0	0	0	0	1	3	3	85	85	95	95	2	2	2	2
9	5	2	0	1	0	2	0	2	3	26	80	90	90	90	2	2	3	2
10	8	3	0	0	0	0	0	0	0	0	30	60	75	70	5	4	3	3
11	6	3	0	0	0	0	0	0	0	0	45	60	40	35	4	4	4	4
12	7	3	0	1	2	0	0	5	18	21	100	100	85	95	3	3	4	4
13	7	4	0	0	0		0	0	0	0	100	100	100		3	3	3	
14	7	3	0	0	0		0	0	0		45	45	45		4	3	4	6
15	11	4	0	0	0	0	0	3	3	0	40	75	40	50	4	3	3	4
16	5	4	0	0	0	0	0	0	0	0	65	85	95	95	3	3	3	2
17	8	4	0	0	0	0	0	0	0	0	45	55	45	55	4	4	4	4
18	8	4	0	0	0	0	0	0	0	0	35	35	35	30	4	4	4	4
19	7	3	0	0	0	0	0	0	0	0	70	65	75	65	3	3	2	2
20	16	4	0	0	0	0	0	0	0	0	55	50	50	45	4	4	4	4
21	13	4	0	0	0	0	0	0	0	0	15	40	40	45	4	4	4	4
22	10	4	0	0	0	0	0	0	0	0	15	30	30	30	4	4	4	4
23	7	4	0	0	0	0	0	0	0	0	55	55	55	55	3	3	3	4

Supplementary Table 4: ARAT responders by cortical involvement or isolated subcortical infarct location.

Infarct Location	ARAT item 2	ARAT item 2	ARAT item 2	ARAT total	ARAT total	ARAT total
	3m	6m	12m	3m	6m	12m
Cortical or mixed	0/12	2/11	1/10	2/12	3/11	3/10
Subcortical only	1/8	1/8	2/10	1/10	1/10	2/10

“Cortical” includes 5 with both cortical and subcortical infarct, and 7 isolated cortical infarcts; no infarct was confirmed on imaging in 1 subject and 2 others had no definite location recorded.

Supplementary Figure 1: Number of subjects exhibiting response on primary and secondary outcome measures at 3, 6 and 12 months divided by baseline NIHSS upper limb motor score (2 or 3 indicates some residual movement, 4 indicates no residual movement). NIHSS signifies National Institutes of Health Stroke Scale.

