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Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: The IST-3 collaborative group. The benefits and harms of intravenous thrombolysis with recombinant tissue plasminogen activator within 6 h of acute ischaemic stroke (the third international stroke trial [IST-3]): a randomised controlled trial. *Lancet* 2012; published online May 23. DOI:10.1016/S0140-6736(12)60768-5.

Web appendix contents:

Web table 1 Additional baseline data

	rt-PA		Control	
	No.	**(%)**	**No.**	**(%)**
Number randomised	1515		1520	
Baseline variables collected before treatment allocation[1]				
Clinician's assessment of pre-randomisation scan				
No evidence of recent ischaemic change	894	(59%)	898	(59%)
Possible evidence of recent ischaemic change	361	(24%)	340	(22%)
Definite evidence of recent ischaemic change	260	(17%)	282	(19%)
Baseline variables collected from pre-randomisation scan				
Lesion territory				
MCA or ACA or Borderzone	589	(39%)	555	(37%)
Posterior	22	(1%)	36	(2%)
Lacunar	11	(1%)	5	(<1%)
Indeterminate[3]	885	(59%)	914	(61%)
Lesion size				
None	885	(59%)	914	(61%)
Small	110	(7%)	97	(6%)
Medium	250	(17%)	250	(17%)
Large	124	(8%)	137	(9%)
Very large	138	(9%)	112	(7%)
Depth of tissue damage				
None	892	(59%)	922	(61%)
Mild	503	(33%)	492	(33%)
Severe	112	(7%)	96	(6%)
Degree of swelling				
None	1152	(76%)	1171	(78%)
Mild Sulcal	283	(19%)	265	(18%)
Mild Ventricular	71	(5%)	73	(5%)
Moderate	1	(<1%)	0	(0%)
Severe[4]	0	(0%)	1	(<1%)
Location of hyperdense arteries				
None	1131	(75%)	1151	(76%)
Anterior	360	(24%)	342	(23%)
Posterior	16	(1%)	17	(1%)
Evidence of atrophy	1161	(77%)	1166	(77%)
Evidence of periventricular lucencies	765	(51%)	782	(52%)
Evidence of old lesions	685	(45%)	651	(43%)
Evidence of non-stroke lesions	73	(5%)	77	(5%)
Baseline variables collected from seven-day form				
Pre-trial history of stroke	354	(23%)	345	(23%)
Pre-trial treatment with aspirin	639	(47%)	667	(49%)
Pre-trial treatment with dipyridamole	66	(5%)	59	(4%)
Pre-trial treatment with clopidogrel	69	(5%)	77	(6%)
Pre-trial treatment with anticoagulants				
Warfarin or other oral anticoagulant	61	(4%)	57	(4%)

	rt-PA		Control	
	No.	**(%)**	**No.**	**(%)**
Heparin[5] (low dose)	15	(1%)	5	(0%)
None of the above	1292	(94%)	1309	(95%)
Pre-trial treatment for hypertension	975	(64%)	979	(65%)
Pre-trial treatment for diabetes	184	(12%)	204	(13%)
Phase of trial in which patient recruited				
Blinded	136	(9%)	140	(9%)
Open	1379	(91%)	1380	(91%)
Patients recruited in centre with pre-trial experience of thrombolysis[6]	575	(38%)	568	(37%)

NIH = National Institutes of Health, TACI= Total Anterior Circulation Infarct, PACI = Partial Anterior Circulation Infarct, LACI = Lacunar Infarct, POCI = Posterior Circulation Infarct, MCA = middle Cerebral Artery, ACA = Anterior Cerebral Artery

1. These variables were collected via the web-based or telephone randomisation system and had to be entered, complete and passed range and consistency checks before the system would issue a treatment allocation. Variables marked with an asterisk* were employed in the minimisation algorithm.
2. Expert panel's blinded assessment of pre-randomisation scan. This assessment was performed by the expert panel members after randomisation & blinded to treatment allocation and all clinical details.
3. Indeterminate because no infarct was visible.
4. Two patients in Control group were randomised at more than 6 hours (protocol violation). One of these was recorded as having severe swelling on the randomisation scan, it was later discovered that the stroke had occurred about 24 hours earlier.
5. Heparin: unfractionated or low-molecular weight heparin.
6. Pre-trial experience of thrombolysis is defined as the centre had, before joining the trial, a protocol for open label rtPA and had treated at least 3 people in the 12 months before joining the trial; 76 (49%) centres met this criterion.

Web table 2 Adherence to treatment protocol and background stroke care

	rt-PA (n= 1515)		Control (n=1520)	
	No·	(%)	No·	(%)
Eligibility deviations				
Dependent pre-stroke[1]	8	(0·5%)	9	(0·6%)
Haemorrhage on pre-randomisation scan	1	(0·1%)	0	(0·0%)
Advanced ischaemic change on pre-randomisation scan[2]	0	(0·0%)	1	(0·1%)
Tumour or non-stroke lesion on pre-randomisation CT[3]	0	(0·0%)	0	(0·0%)
Pre-randomisation low dose heparin	16	(1·1%)	6	(0·4%)
Systolic BP <90 or >220 mmHg or diastolic BP <40 or >130 mmHg	0	(0·0%)	0	(0·0%)
Glucose outside allowable limits (3·0 to 20 mmol/l)	0	(0·0%)	0	(0·0%)
Thrombolysis for stroke within previous 14 days	0	(0·0%)	1	(0·1%)
Infusion compliance among those allocated rt-PA[4]				
Did not get bolus	26	(1·7%)	·	
Got bolus, but did not start infusion	4	(0·3%)	·	
Got bolus, started infusion, but halted, wrong total dose[5]	29	(1·9%)	·	
Got bolus, started infusion, but halted, right total dose	62	(4·1%)	·	
Got bolus and infusion, wrong total dose[5]	45	(3·0%)	·	
Got bolus and infusion, right dose	1348	(89·0%)	·	
Infusion compliance among those allocated placebo or open control[6]				
Blinded phase : got bolus, but did not start infusion	·		1	(0·1%)
Blinded phase : got bolus, started infusion, but halted	·		6	(0·4%)
Blinded phase : got bolus and planned infusion	·		133	(8·8%)
Open phase : did not receive rtPA	·		1368	(90·3%)
Open phase : received at least some rtPA	·		7	(0·5%)
Treatments given within 24 h				
Double-blind phase				
Aspirin given	12	(8·8%)	10	(7·1%)
Other antiplatelet given	1	(0·7%)	0	(0·0%)
No antiplatelet given	123	(90·4%)	130	(92·9%)
Low dose heparin for DVT prophylaxis given	6	(4·4%)	4	(2·9%)
Full dose heparin given[7]	1	(0·7%)	0	(0·0%)
Intravenous fluids given[8]	11	(73·3%)	8	(47·1%)
Insulin given[8]	0	(0·0%)	1	(5·9%)
Open phase[9]				
Aspirin given	183	(13·3%)	1044	(75·8%)
Other antiplatelet given	53	(3·8%)	218	(15·8%)
No antiplatelet given	1167	(84·8%)	271	(19·7%)
Low dose heparin for DVT prophylaxis given	46	(3·3%)	223	(16·2%)
Full dose heparin given	17	(1·2%)	52	(3·8%)
Intravenous fluids given	838	(62·1%)	804	(59·4%)
Insulin given	96	(7·1%)	99	(7·3%)
Other treatments given between 24 h and 7 days				
Aspirin given	1114	(73·8%)	1284	(84·7%)
Other antiplatelet given	318	(21·1%)	401	(26·5%)
Low dose heparin or LMWH for DVT prophylaxis given	315	(20·9%)	406	(26·8%)
Full anti-coagulation[10]	117	(7·7%)	122	(8·1%)
Any treatment to lower blood pressure	890	(58·9%)	889	(58·7%)
Any non-trial thrombolysis	3	(0·2%)	0	(0·0%)

	rt-PA (n= 1515)		Control (n=1520)	
	No·	**(%)**	**No·**	**(%)**
Antibiotics	378	(27·7%)	361	(26·4%)
Feeding via nasogastric tube or percutaneous gastronomy	256	(18·8%)	304	(22·2%)
Place of treatment in 7 days since randomisation	**N [11] (%)**	**Median stay[12]**	**N [11] (%)**	**Median stay[12]**
	1392		1402	
Admissions area[13]	30 (2·2%)	2	40 (2·9%)	1
High dependency ward, intensive care ward or critical care area	328 (23·6%)	1	237 (16·9%)	1
Stroke unit or stroke rehabilitation unit	1248 (89·7%)	6	1252 (89·3%)	6
General Ward[14]	215 (15·4%)	4	219 (15·6%)	5

1. In the early part of the trial, patients with a minimal degree of pre-stroke dependency could be included. After a protocol amendment to change eligibility, the randomisation programme was changed in September 2004 and such patients could not be included in the remainder of the trial.
2. Marked degree of ischaemic change on pre-randomisation CT or MR incompatible with onset less than 6 hours previously.
3. Tumour or non-stroke lesion sufficient to account for symptoms leading to randomisation.
4. Base of percentages is number with infusion record (1514).
5. Dose violations occur when dose given is greater than 10% above or below the prescribed dose, or when a Control patient in the Open phase received any dose of rt-PA.
6. Base of percentages is number with infusion record (1515). .
7. Full-dose unfractionated heparin or high-dose low molecular weight heparin.
8. Questions on intravenous fluids and insulin were only added in 2004. Hence few participants in the blinded phase were asked these questions (15 rt-PA, 17 Control).
9. Patients in the control arm of the open phase who receive these drugs are not protocol violators, but are shown here for information. Base of percentages is number with valid seven-day follow-up in given trial phase and treatment group.
10. Full-dose unfractionated heparin, high-dose low molecular weight heparin or oral anticoagulants.
11. N is the number of patients who spent at least one night on the particular type of ward. The base of percentages is the number of patients who spent at least one night in any of these ward types This question was not asked in the early part of the trial (pre 2003).
12. Median number of nights spent among patients who stayed at least one night in given type of ward.
13. Accident and Emergency Department or Medical admissions unit.
14. General Ward: Neurology Ward, Geriatric Medicine Ward, General Internal Medicine Ward, Neurosurgical Ward, Geriatric Ward, Rehabilitation Ward or Other Ward.

Webtable 3: Outcomes at six months for patients with known disability status

	rt-PA		Placebo		Adjusted analysis[1]		Unadjusted analysis[2]		
	N	**(%)**	**N**	**(%)**	**OR (95% CI)**	**P**	**OR (95% CI)**	**P**	**Difference per 1000 (95% CI)**
No. randomised	1515		1520						
No. with known 6 month disability status	1473		1466						
Oxford Handicap Score									
0	137	(9%)	116	(8%)					
1	225	(15%)	204	(13%)					
2	183	(12%)	200	(13%)					
3	234	(15%)	192	(13%)					
4	115	(8%)	140	(9%)					
5	171	(11%)	207	(14%)					
6 (Died before 6 months)	408	(27%)	407	(27%)	0·94 (0·79 , 1·13)	0·533	1.00 (0·85 , 1·18)	0·969	1 (-31, 32)
Alive and favourable outcome (0+1)	362	(25%)	320	(22%)	1·25 (1·03 , 1·51)	0·026	1·17 (0·98 , 1·39)	0·078	28 (1, 58)
Alive and independent (0+1+2)	545	(37%)	520	(35%)	1.14 (0.95 , 1.36)	0.160	1.07 (0.92 , 1.25)	0.389	15 (-19, 50)
Total deaths < 7 days	163	(11%)	107	(7%)	1·60 (1·22 , 2·08)	0·001	1·59 (1·22 , 2·07)	<0·001	-37 (-57, -17)

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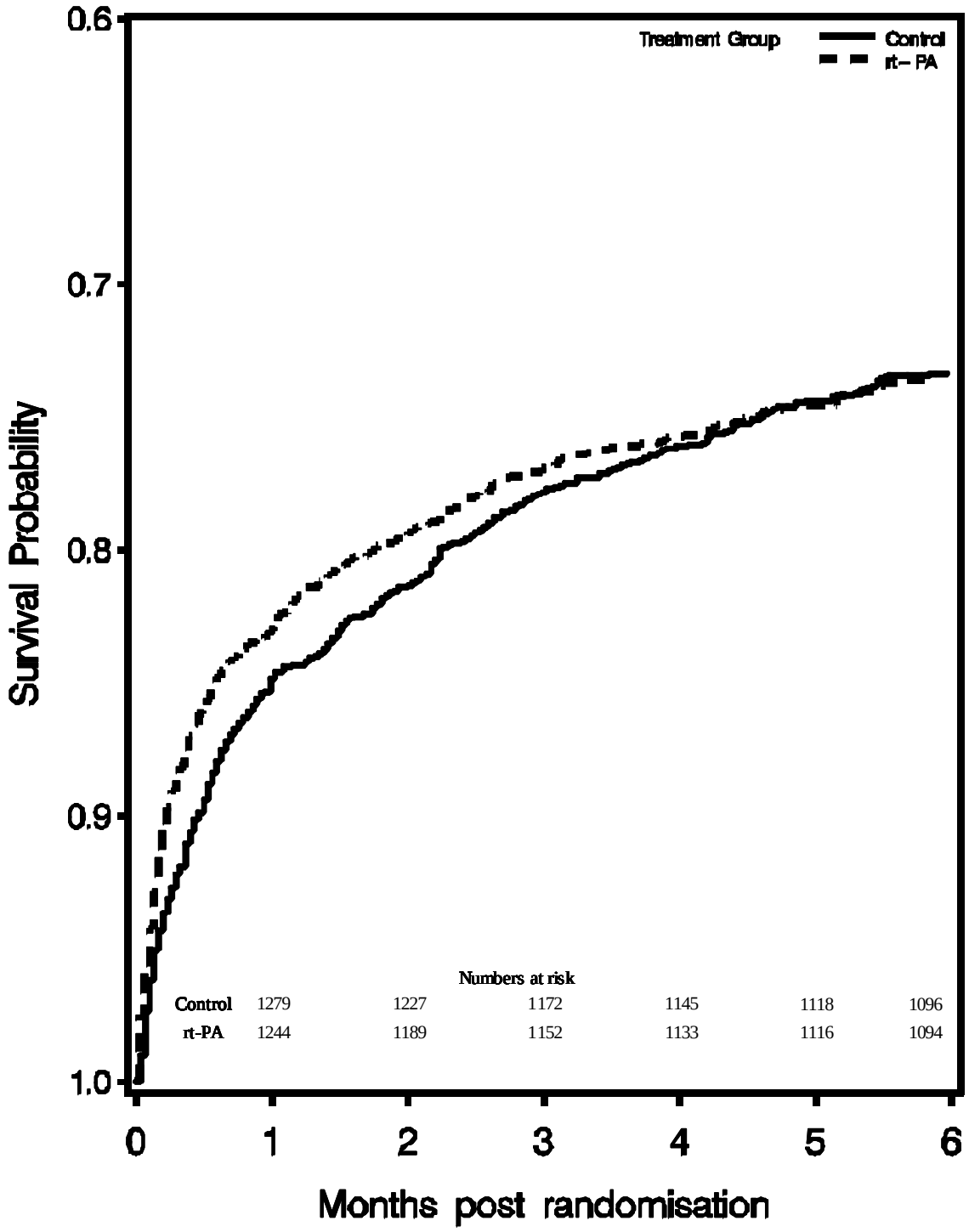
Notes:

1. OR = Odds Ratio. Odds ratio and p value calculated from logistic regression after adjusting for age (linear), NIHSS (linear), time (linear) and presence/absence of visible acute ischaemic change on baseline scan as judged by the expert reader. The two cases with delay time greater than 6 hours were omitted from the adjusted analysis.
2. Significance p value calculated from test of difference between percentages for rt-PA and Control, using normal approximation.
3. Oxford Handicap Scale:
0. No symptoms at all. 1. Symptoms, but these do not interfere with everyday life. 2. Symptoms which have caused some changes in lifestyle but still able to look after oneself. 3. Symptoms which have significantly changed lifestyle and need some help in looking after oneself. 4. Severe symptoms requiring help from other people but not so bad as to need attention day and night. 5. Severe handicap needing constant attention day and night.
4. Primary outcome shown in bold

Web Figure 1



Web Figure. Kaplan Meier plot of survival to six months. The dotted line is the treatment group and the solid line the control. Deaths at day 0 excluded from at risk at day 0. Logrank test of difference in survival curves: P=0.83

List of participating hospitals in each country.

Figures in parentheses are the number of patients recruited in the country or by the centre. ***UK*** *(1447)* Royal Hallamshire Hospital (118): G Venables, C Blank, H Bowler, C Doyle, K Endean, K Harkness, E Parker, M Randall. University Hospital of North Staffordshire (97): C Roffe, N Ahmad, A Arora, S Brammer, J Chembala, B Davies, S Ellis, E Epstein, K Finney, C Jackson, C Jadun, R Kinston, H Maguire, I Memon, I Natarajan, M Poulson, R Sanyal, S Sills, A Vreeburg, E Ward. Western General Hospital (95): P Sandercock, R Al-Shahi Salman, R Davenport, M Dennis, P Hand, S Hart, I Kane, S Keir, M MacLeod, L McKinlay, H Milligan, E Sandeman, J Stone, C Sudlow, P Taylor, J Wardlaw, C Warlow, W Whiteley, A Williams. 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