

Online-Only Supplements list

Table S1. Number of patients with adverse events (by system organ class) up to 90 days visit

Table S2. Number of patients with serious adverse events (by system organ class) up to 90 days visit

Table S3. Result of quality indicators tested between rhTNK-tPA and Melalyse

Table S1. Number of patients with adverse events (by system organ class) up to 90 days visit

System organ class	Tenecteplase (N=76)	Alteplase (N=61)	P value
Overall	70 (92.1%)	56 (91.8%)	>0.99
Metabolism and nutrition disorders	39 (51.3%)	31 (50.8%)	0.95
Ear and labyrinth disorders	0	0	..
Hepatobiliary disorders	4 (5.3%)	4 (6.6%)	>0.99
Infections and infestations	23 (30.3%)	20 (32.8%)	0.75
Investigations	19 (25.0%)	24 (39.3%)	0.07
Nervous system disorders	23 (30.3%)	13 (21.3%)	0.24
Injury, poisoning and procedural complications	5 (6.6%)	5 (8.2%)	0.98
Musculoskeletal and connective tissue disorders	2 (2.6%)	6 (9.8%)	0.14
Surgical and medical procedures	1 (1.3%)	0	>0.99
Congenital, familial and genetic disorders	0	1 (1.6%)	0.45
Respiratory, thoracic and mediastinal disorders	16 (21.1%)	18 (29.5%)	0.25
Psychiatric disorders	13 (17.1%)	9 (14.8%)	0.71
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (1.6%)	0.45
Immune system disorders	0	1 (1.6%)	0.45
Endocrine disorders	1 (1.3%)	0	>0.99

System organ class	Tenecteplase (N=76)	Alteplase (N=61)	P value
Skin and subcutaneous tissue disorders	6 (7.9%)	4 (6.6%)	>0.99
General disorders and administration site conditions	10 (13.2%)	5 (8.2%)	0.36
Social circumstances	0	0	..
Renal and urinary disorders	15 (19.7%)	8 (13.1%)	0.30
Reproductive system and breast disorders	0	1 (1.6%)	0.45
Gastrointestinal disorders	35 (46.1%)	32 (52.5%)	0.46
Cardiac disorders	10 (13.2%)	15 (24.6%)	0.09
Vascular disorders	7 (9.2%)	9 (14.8%)	0.32
Blood and lymphatic system disorders	16 (21.1%)	7 (11.5%)	0.14
Eye disorders	0	1 (1.6%)	0.45

Table S2. Number of patients with serious adverse events (by system organ class) up to 90 days visit

System organ class	Tenecteplase (N=76)	Alteplase (N=61)	P value
Overall	15 (19.7%)	16 (26.2%)	0.37
Metabolism and nutrition disorders	0	0	..
Ear and labyrinth disorders	0	0	..
Infections and infestations	2 (2.6%)	2 (3.3%)	>0.99
Investigations	0	1 (1.6%)	0.45
Nervous system disorders	6 (7.9%)	9 (14.8%)	0.20
Injury, poisoning and procedural complications	4 (5.3%)	3 (4.9%)	>0.99
Musculoskeletal and connective tissue disorders	0	1 (1.6%)	0.45
Congenital, familial and genetic disorders	0	0	..
Respiratory, thoracic and mediastinal disorders	3 (4.0%)	1 (1.6%)	0.63
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	..
General disorders and administration site conditions	2 (2.6%)	0	0.50
Renal and urinary disorders	0	1 (1.6%)	0.45
Gastrointestinal disorders	1 (1.3%)	0	>0.99
Cardiac disorders	3 (4.0%)	3 (4.9%)	>0.99
Vascular disorders	0	0	..
Eye disorders	0	0	..

Table S3. Result of quality indicators tested between rhTNK-tPA* and Metalyse

Item	Specification	rhTNK-tPA2017110402	rhTNK-tPA2018120102	rhTNK-tPA201905012	Metalyse 804823	Metalyse 902235
Potency†	Indicated amount%	91	95	97	106	101
Protein content†	Indicated amount%	101	99	101	100	96
Purity (electrophoresis)	Monomer content%	95.6	96.0	95.7	...‡	
	Monomer content%	98.4	98.2	98.5	98.4	99.0
Purity (HPLC)	Aggregates content%	1.5	1.6	1.3	0.9	0.6
	Two-chain content%	4.6	8.8	6.5	41.6	34.5
Molecular size	KD Single-chain	69.2	68.6	67.9	68.2	70.7
	KD Two-chain	35.4	33.8	33.5	32.2	33.7
Type I/ Type II content (home made)	Type I%	29.0	29.6	30.3	29.1	29.4
	Type II%	71.0	70.4	69.7	70.9	70.6
Type I/ Type II content (commercial)	Type I%	40.9	41.0	41.2	44.1	42.2
	Type II%	59.1	59.0	58.8	55.9	57.8
Isoelectric point	/	5.9-6.9	5.8-6.9	6.0-6.9	5.8-7.0	5.9-7.0
Tryptic-peptide HapMap	/	Met specification	Met specification	Met specification	Same with rhTNK-tPA	Same with rhTNK-tPA
PeptideHapMap	/	Met specification	Met specification	Met specification	Same with rhTNK-tPA	Same with rhTNK-tPA
Sialic acid	%	98	105	100	82	91

The result was tested in China Shijiazhuang Pharmaceutical Company Recomgen Pharmaceutical (Guangzhou). Abbreviations: rhTNK-tPA=recombinant human TNK tissue-type plasminogen activator. HPLC= high performance liquid chromatography.

*rhTNK-tPA: the product name of the Chinese version of tenecteplase. †The results of potency and protein content were tested in comparison to pharmacopoeia standards.

‡The Metalyse Hapmap has fragment stripe besides monomer and aggregates, which interfered with the result of purity.