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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.

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Supplementary appendix

Supplementary table 1 – Recruitment by country

Country	Participants Recruited N (%)	Average per month
Total number recruited	2325	
United Kingdom	1910 (82.2%)	32.93
Georgia	141 (6.1%)	3.28
Italy	96 (4.1%)	1.92
Malaysia	46 (2.0%)	1.64
Switzerland	46 (2.0%)	1.53
Denmark	39 (1.7%)	2.17
Republic of Ireland	17 (0.7%)	0.65
Hungary	9 (0.4%)	0.64
Turkey	9 (0.4%)	0.33
Sweden	8 (0.3%)	0.29
Poland	3 (0.1%)	0.19
Spain	1 (0.0%)	0.06

Supplementary table 2 – Adherence

	TXA	Placebo	p
Number of participants randomised	1161	1164	
All randomised treatment received as intended, n (%)	1101 (94.8%)	1106 (95.0%)	0.96
Some randomised treatment received, n (%)	49 (4.2%)	51 (4.4%)	0.66
No randomised treatment received, n (%)	9 (0.8%)	6 (0.5%)	0.48
Not known what treatment received, n (%)	2 (0.2%)	1 (0.1%)	0.54
Protocol violation submitted for incorrect drug administration*, n (%)	31 (2.7%)	26 (2.2%)	0.56
Time until first dose (minutes), median [IQR] {range}	21 [13, 33] {1, 167}	21 [13, 32] {1, 196}	0.49

*Protocol violations were investigator reported. Data are number (%), median [IQR].

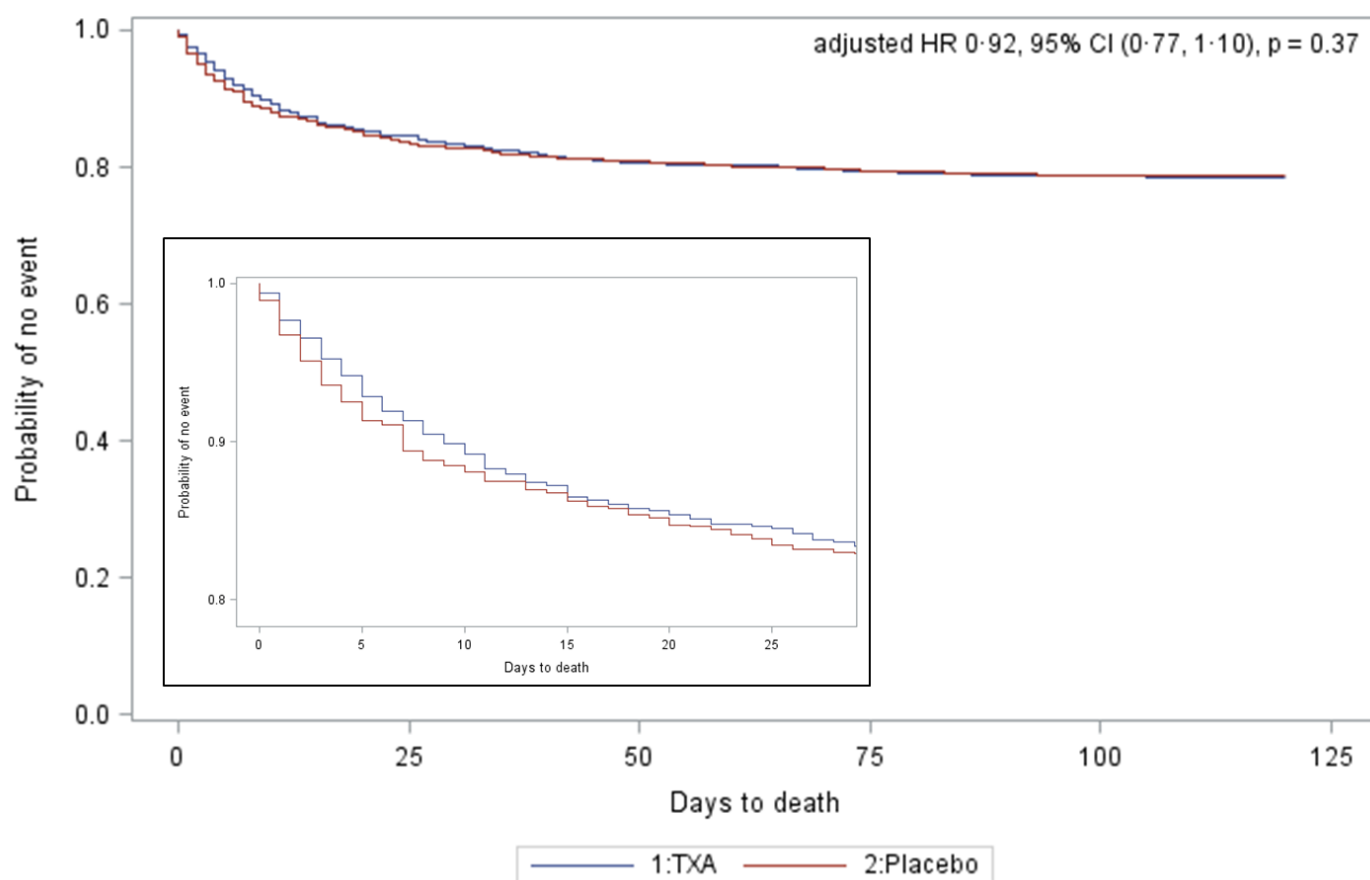
Supplementary table 3 – Serious adverse event information

	Median days to event [IQR]	TXA 1161	Placebo 1164	p
By day 2		379 (32.6%)	417 (35.8%)	0.0272
By day 7		456 (39.3%)	497 (42.7%)	0.0200
By day 90		521 (44.9%)	556 (47.8%)	0.0393
Safety outcomes				
Death	1 [0, 15]	250 (21.5%)	249 (21.4%)	0.60
ACS or MI	5 [1, 53]	11 (0.9%)	6 (0.5%)	0.24
Deep vein thrombosis (DVT)	15 [10, 34]	19 (1.6%)	14 (1.2%)	0.41
Pulmonary embolism (PE)	16 [8, 29]	20 (1.7%)	23 (2.0%)	0.58
VTE (combined DVT/PE)	16 [10, 30]	39 (3.4%)	37 (3.2%)	0.98
Seizure / convulsions	1 [0, 3]	77 (6.6%)	85 (7.3%)	0.44
Ischaemic stroke or TIA	9 [2, 52]	16 (1.4%)	11 (0.9%)	0.27
SAEs by subcategory				
Blood and lymphatic system disorders	0 [0, 4]	1 (0.1%)	2 (0.2%)	0.41
Cardiac disorders	1 [1, 2]	14 (1.2%)	10 (0.9%)	0.48
Gastrointestinal disorders	1 [0, 2]	12 (1.0%)	9 (0.8%)	0.59
General disorders and administration site conditions	2 [1, 3]	2 (0.2%)	2 (0.2%)	0.95
Immune system disorders	0 [0, 1]	1 (0.1%)	2 (0.2%)	0.51
Infections and infestations	2 [1, 3]	98 (8.4%)	116 (10.0%)	0.14
Injury, poisoning and procedural complications	1 [1, 3]	7 (0.6%)	10 (0.9%)	0.53
Metabolism and nutrition disorders	4 [1, 7]	0	2 (0.2%)	0.99
Musculoskeletal and connective tissue disorders	1 [1, 1]	0	1 (0.1%)	0.99
Neoplasms benign, malignant and unspecified	4 [1, 5]	3 (0.3%)	3 (0.3%)	0.89
Nervous system disorders	1 [0, 1]	171 (14.7%)	189 (16.2%)	0.24
Psychiatric disorders	4 [3, 5]	1 (0.1%)	4 (0.3%)	0.26
Renal and urinary disorders	2 [1, 4]	14 (1.2%)	17 (1.5%)	0.66
Respiratory, thoracic and mediastinal disorders	1 [1, 2]	4 (0.3%)	3 (0.3%)	0.72
Skin and subcutaneous tissue disorders	5 [5, 5]	2 (0.2%)	0	0.99

	Median days to event [IQR]	TXA 1161	Placebo 1164	p
Vascular disorders	1 [0, 2]	7 (0·6%)	9 (0·8%)	0·64
Miscellaneous	1 [0, 3]	7 (0·6%)	6 (0·5%)	0·81

Data are number (%), median [IQR]. This table gives details on the serious adverse events experienced up until each participant's day 7 follow-up; safety outcomes and death are collected up until day 90. The numbers given in each group are per participant, as opposed to the total number of events. Categorisation is according to Medical dictionary for regulatory authorities (MedDRA). The by site section will be given for number of participants in each row; if someone had an event in both the cardiovascular and nervous system categories then they would appear twice, once in each of these categories. Comparisons will be done using binary logistic regression.

Supplementary figure 1 – Plot of cumulative mortality up to 120 days



1	1161	994	950	932	919	913	911
2	1164	991	949	934	923	917	916

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Royal London Hospital: T Harrison, A A Salek-HAddadi, A Sivagnanartnam, C Dowty, D Hove, E Quelch, E Erumere, G Grimwood, G Bellhouse, G Auld, H Syed, I Pope, I Skene, J Pott, J Pincott, J Richards, K Saastamoinen, K Gunn, L Cuenoud, L Howaniec, L Argandona, L Dennis, M Chiriac, N Stewart, O Boulton, O Redjep, P Gompertz, P Daboo, R Duncombe-Anderson, R Yadava, R Erande, R Michael, R Icart Palau, S Al-Saadi, S Amlani, T Harris

Royal Preston Hospital: H Emsley, A McLoughlin, A Cullen, B Gregary, S Ahmed, S Philip, S Puneekar, S Raj, S Sultan, Z Subhani, D Doyle

Royal Stoke University Hospital: R Dharmarajah, A Barry, A Butler, A Remegoso, A Morris, A Warusevitane, C Lambert, C Causley, C Roffe, C Bosanko, F G Alipio, G K Muddegowda, H Maguire, I Massey, I Natarajan, J Chembala, J Grocott, J Hiden, J Norton, K Hunter, K Finney, K Castro-Foskett, N Ahmad, N Abano, P Ferdinand, R Carpio, R Sanyal, R Varquez, R Hall, R Kinston, S Stevens, S Lyjko, S Huda, T James, U Ghani

Royal Sussex County Hospital: I Kane, A Pitt Ford, D Hansen, D Mullan, E Barbon, F Caddy, J Breeds, L Behar, L Latter, L Ortiz-Ruiz de Gordo, N Gainsborough, P Thompson, S Hervey

Royal United Hospital Bath NHS Trust: S Al-Nahhas, A Cross, A Wedgwood, B Madigan, C Hardy, C Peter, C Taylor, D Watson, D Howcroft, D Button, D Williamson, E Day, E Brown, E Gilby, E Carver, F Beech, H Newton, J Choulerton, J Jones, J Avis, J Bareham, K Peacock, K Manning, L Shaw, L Gbadamoshi, M Price, N V Kumar, N Adams, N Jakeman, P Paterson, P Kaye, R Porada, R Oaten, R Furse, S Nushaj, S McCann, S Lucas, T Slade

Royal Victoria Infirmary (RVI): A Dixit, A Barkat, A Gani, A Dyker, C Hubbuck, C Hays, C Tunnell, C Stevenson, E Horsley, E Elkin, G Ford, G M Smith, H Curry, H Guy, J L Byers, J Bird, J Davis, K Storey, L Giraldo, L Finlay, M Davis, M Fawcett, M Hossain, S Dima, S Louw, S Woodward, S Crawford, T Thompson, V Hogg

Russells Hall Hospital: S Kausar, A Salam, A Cole, A C Gregory, A K Banerjee, C Allcock, D Beckley, L Kadiki, M Maw, M Rasappan, R Gidda, S Fullwood, S Merotra

Salford Royal Hospital: C Smith, A Parry-Jones, A Ahmad, A K Kishore, A Hall, A Ingham, A Suman, D Sen, E Campbell, J Barker, J Perez, J M Morell, J Kallingal, K Shaw, L Harrison, M Massyn, M Punter, M Johnes, R Jarapa, S Marshall, S Arshad, T Marsden, V Ellison, V O'Loughlin, Y Pai, Z Naing

Salisbury District Hospital: T Black, A Anthony, C Clarke, D Mead, R Fennelly

Scarborough General Hospital: J Paterson, E Temlett, K Deighton, L Brown, S Dyer

Sheffield Teaching Hospitals NHS Foundation Trust: K Harkness, A Ali, SC Blank, C Kamara, C Doyle, D Sokhi, E Richards, G Dunn, J Howe, J Janbieh, K Gill, K Dakin, M Meegada, M Randall, M Khan, R Lindert, S Bell, S Duty

South Devon Healthcare: B Bhaskaran, A Saulat, G Ayres, H Shiels, H Bearne, J Buxton, J France, K Horan, P Fitzell, S Szabo

South West Acute Hospital: B Keegan, C Blair, J Kelly, M Doherty, S Grimes

Southampton General Hospital: N Weir, R Marigold, A Blades, A Walters, B Watkins, C Cox, C Allen, D Whittaker, E Battersby Wood, F Smith, G Howard, I Gartrell, J Mitchell, L Sykes, M Brown, P Crawford, R Creeden, S Egerton, S Smith, S Evans, V Pressly

Southend University Hospital NHS Fdt Trust: P Guyler, A Muhammad, A Siddiqui, A Siddiqui, C Hmu, D Ngo, D Sinha, K X Ng, M Ramjee, N Menon, R Prabakaran, S Alam, S Tysoe, S Kelavkar, S Rashmi, S Kunhunni, S Shah, T Loganathan

Southern Health & Social Care Trust: M McCormick, C Douglas, D Craig, M Goggin

St George's Healthcare NHS Trust: B Clarke, A Blight, A Thompson, A Dawson, A Pereira, A Nitkunan, B Moynihan, B Patel, C Lovelock, C Medcraft, C Watchurst, C Loughran, C Lambe, C Orefo, F Watson, G Cluckie, K Kennedy, K Kong, K Moodley, L O'Duffy, L Zhang, L Young, M Yogarajah, N Jeyaraj, N Clarke, N Gilliat, N Chopra, N Dayal, P O'Mahony, R Williams, R Ghatala, S Shribman, S Rounding, S Trippier, T Adedoyin, T Hardiman, U Khan, V Jones

Stepping Hill Hospital: J Vassallo, A Khan, A Hasan, D Morse, D Leonard, H Cochrane, J Curtis, J Awolesi, K Dizayee, M Malik, N Mumtaz, S Krishnamoorthy, S Qamar

Sunderland Royal Hospital: J O'Connell, B Mokoena, A Smith, C Fox, D Gulliver, E Osborne, M Bokhari, M Myint, R O'Brien, S Crawford

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Queen Elizabeth Hospital Birmingham: D Sims, C Sutton, E Littleton, E Hardy, J Cunningham, J Hurley, J McCormack, J Khaira, M Wilmot, M Bates

The Royal Surrey County Hospital: K Pasco, A Blight, B Olga, C Peixoto, G Longwe, J Corns, S Bradfield

United Lincolnshire Hospitals Trust: M Soliman, C Hewitt, I Wahishi, J Sharma, J Hindle, R Brown, S Arif, S Leach, S Butler

University College London Hospitals NHS Fdn Trust: D Werring, A Rafique, A Ashton, A Sivagnanartnam, A Shukla, A Banaras, B Athwal, C Hogan, C Watchurst, D Burrage, D Epstein, D Turner, D Austin, E Elliott, I Jones, J Fleming, K Patel, L Benjamin, L Howaniec, L Latter, L Potter, L Ginsberg, L Crook, M Bhargava, M Brezitski (Abramova), M Sayed, N Francia, N Oji, R Erande, R Perry, R Luder, R Laird, S Al-Saadi, S Mufti, S Feerick, S Tshuma, T Yates, T Enes

University Hospital Aintree: T Hlaing, C Cullen, D Shackcloth, J Peters, R Kumar, R Durairaj, T Fluskey, V Sutton, Z Mellor

University Hospital of North Durham: D Bruce, B Esi, E Brown, G Shim, G M Smith, G Rogers, K Z Nyo, M Dhakal, S Dima, S Clayton, Y Pai

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Watford General Hospital: D Collas, E Walker, M Bhandari, S Sundayi, S Gill

West Suffolk Hospital: A Nicolson, A Azim, D Singh, E Stebbings, J Imam, J White, L Wood, M Krasinska, S Alam

William Harvey Hospital: T Webb, A Verrion, A Thomson, D Hargroves, E Beranova, H Rudenko, I Balogun, L Cowie, S Walker, T Cosier

Worthing Hospital: N Sengupta, C Dewar, J Margalef, M Metiu

Yeovil District Hospital: K Rashed, C Smith, C Buckley, D Wood, L Balian, N Marks, S Board, T Pitt-Kerby

York Hospital: P Wanklyn, C Anazodo, J Coyle, K Deighton, L Doughty, M O'Neill, M Porteous, M Keeling, N Dyer, P Willcoxson, P Clark-Brown, P Inns, R Mir