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Asundexian for secondary stroke prevention in Chinese participants: Results of a subgroup analysis of the OCEANIC-STROKE trial

Yi Dong,[1] I-Hui Lee,[2,3] Mukul Sharma,[4] Ashkan Shoamanesh,[4] Angela Wang,[5] Karleen Schulze,[5] Lizhen Xu,[5] Eva Muehlhofer,[6] Christoph Neumann,[6] Qiang Dong[1] on behalf of Chinese Investigators of OCEANIC-STROKE

[1]Department of Neurology and National Center for Neurological Disorders, Huashan Hospital, Fudan University, Shanghai, China; [2]Department of Neurology, Taipei Veterans General Hospital, Taipei City, Taiwan; [3]National Yang Ming Chiao Tung University, Taipei City, Taiwan; [4]Department of Medicine, Population Health Research Institute, McMaster University, Hamilton, ON, Canada; [5]Population Health Research Institute, McMaster University, Hamilton, ON, Canada; [6]Bayer AG, Wuppertal, Germany



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Disclosure

This study was funded by Bayer AG.
Asundexian is not yet approved for use in secondary stroke prevention.

High burden of stroke in China

- China has about 20% of the global population, but annual new stroke cases are 34% of the world total[1,2]
- Stroke ranks as the leading cause of death in China[3]
- 3.4 million first-ever strokes occurred in China in 2020 (505 per 100,000 person-years), with ischemic stroke representing the large majority[4]
- Population-based studies show higher stroke incidence in Chinese than White populations aged 45–74 years[5]
- Stroke occurs at a younger age among Chinese individuals, more often in their 60s than 70s[5]

1. Zhu Z, et al. *Chin Med J*. 2025;138(20):2588–2595; 2. Wang W, et al. *Circulation*. 2017;135(8):759–771; 3. The GBD 2016 Lifetime Risk of Stroke Collaborators. *N Engl J Med*. 2018;379(25):2429–2437; 4. Tu WJ, et al. *JAMA Netw Open*. 2023;6:e231455; 5. Tsai CF, et al. *Neurology*. 2013;81:264–272.

High stroke recurrence and differences in stroke mechanism

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- Among 28-day stroke survivors in China, 41% had a recurrent stroke within 5 years[1]
- In European- and USA-based studies, 5-year recurrent stroke rates have been reported between 14–26%[2]
- Chinese populations have higher proportions of small-vessel (33% vs 19%) and atherothrombotic ischemic stroke (25% vs 15%) and lower proportions of cardioembolic stroke (16% vs 26%) compared to White populations[3]
- Intracranial atherosclerosis is more common in Chinese, compared to White, populations[4]

1. Chen Y, et al. *Lancet Glob Health*. 2020;8(4):e580–e590; 2. Kolmos M, et al. *J Stroke Cerebrovasc Dis*. 2021;30(8):105935; 3. Tsai CF, et al. *Neurology*. 2013;81:264–272;
4. Leng X et al. *J Neurol Neurosurg Psychiatry*. 2021;92:590–597.

Differences in the efficacy and safety of antiplatelet therapy

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CHANCE (Chinese population, 2013)

- **Design:** Enrollment within **24 h** of onset; clopidogrel loading 300 mg, then 75 mg/d for 90 d; **aspirin only for the first 21 d (75 mg/d)**
- **Efficacy:** DAPT significantly reduced 90-day stroke recurrence (8.2% vs **11.7%**; HR 0.68, P<0.001)
- **Safety:** **No significant increase in moderate/severe hemorrhage** between DAPT and aspirin monotherapy groups

POINT (predominantly American population, 2018)

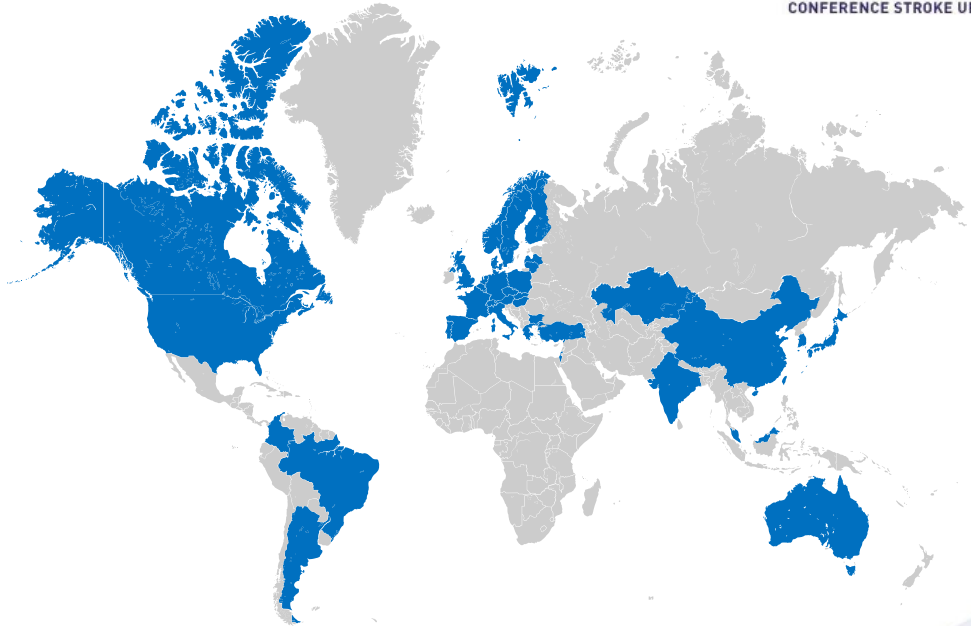
- **Design:** Enrollment within **12 h**; clopidogrel loading 600 mg; **both aspirin and clopidogrel given for full 90 d**
- **Efficacy:** DAPT reduced composite ischemic vascular events (stroke/MI/vascular death) (5.0% vs **6.5%**; HR 0.75, P=0.02).
- **Safety:** **Major bleeding risk was significantly higher in DAPT group**, leading to early trial termination

d, days; DAPT, dual antiplatelet therapy; h, hours; HR, hazard ratio; MI, myocardial infarction.

Sharma M, et al. *N Engl J Med*. 2026;394(15):1467–1479.

OCEANIC-STROKE

- Design
  - Placebo-controlled
  - Double-blinded
  - Event-driven Phase III RCT
- Comparing asundexian 50 mg once daily and placebo
- Patients with noncardioembolic stroke or high-risk TIA
  - Planned for antiplatelet therapy – single or ASA + P2Y12 inhibitor (clopidogrel, ticagrelor, prasugrel)



37 Countries/Regions, 702 Sites

ASA, acetylsalicylic acid; P2Y12, purinergic receptor Y12; RCT, randomized controlled trial; TIA, transient ischemic attack.
Sharma M, et al. *N Engl J Med*. 2026;394(15):1467–1479.

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OCEANIC-STROKE: Study design

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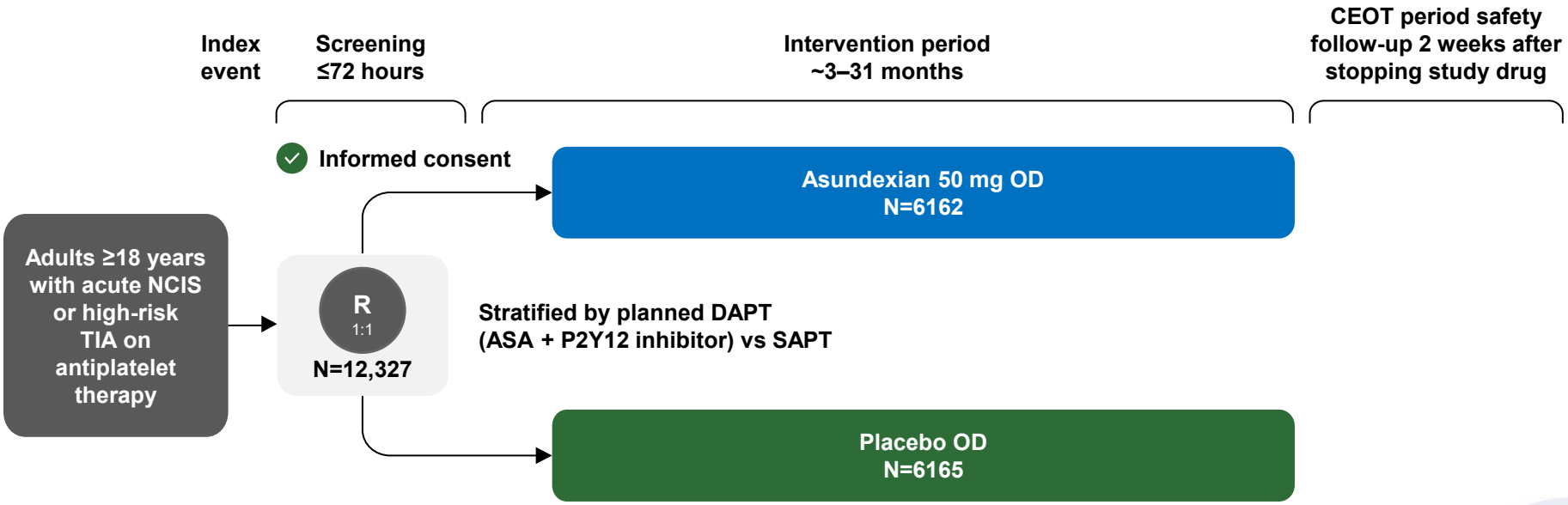

ASA, acetylsalicylic acid; CEOT, common end of treatment; DAPT, dual antiplatelet therapy; NCIS, noncardioembolic ischemic stroke; OD, once daily; P2Y12, purinergic receptor Y12; R, randomized; SAPT, single antiplatelet therapy; TIA, transient ischemic attack.

Sharma M, et al. *N Engl J Med*. 2026;394(15):1467–1479.

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Objective and methods

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Objective

- To evaluate the efficacy and safety profile of asundexian among Chinese participants in East Asia in the OCEANIC-STROKE trial

Methods

- Analysis restricted to self-defined Chinese participants in East Asia

Outcomes

- Ischemic stroke; ISTH major bleeding
  - **Secondary outcome**
    - Hemorrhagic stroke

Statistical analysis

- Cumulative incidence estimated by the Aalen–Johansen method; csHRs derived from stratified Cox model
- Prespecified subgroup analyses performed for ischemic stroke endpoint

csHR, cause-specific hazard ratio; ISTH, International Society on Thrombosis and Haemostasis.

Results

Baseline demographics

	All OCEANIC participants	Chinese participants
Participants, n	12,327	1451
Age, mean (SD), years	67.6 (10.8)	62.9 (10.0)
Female sex, n (%)	4110 (33.3)	399 (27.5)
Medical history, n (%)		
Previous stroke or TIA	2655 (21.5)	495 (34.1)
Diabetes	4249 (34.5)	594 (40.9)
Hypertension	9805 (79.5)	1159 (79.9)
Hyperlipidemia	7651 (62.1)	707 (48.7)
Current tobacco use	3309 (26.8)	536 (36.9)
Index event, n (%)†	12,325	1450
Ischemic stroke	11,677 (94.7)	1410 (97.2)
TIA	648 (5.3)	40 (2.8)
Stroke subtype (TOAST classification), n (%)‡		
Large-artery atherosclerosis	4996 (42.8)	610 (43.3)
Small-vessel occlusion (lacune)	2639 (22.6)	677 (48.0)
Stroke of other determined etiology	349 (3.0)	15 (1.1)
Stroke of undetermined etiology	3496 (29.9)	106 (7.5)
Cardioembolism	196 (1.7)	2 (0.1)
IVT and/or EVT, n (%)‡	3201 (27.4)	198 (14.0)
NIHSS at randomization, median (IQR)‡	3.0 (2.0–6.0)	3.0 (2.0–5.0)
Planned antiplatelet at randomization, n (%)		
DAPT	7712 (62.6)	985 (67.9)

*% out of no. of index event. †For those with index event of ischemic stroke only.
DAPT, dual antiplatelet therapy; EVT, endovascular thrombectomy; IQR, interquartile range; IVT, intravenous thrombolysis; NIHSS, National Institutes of Health Stroke Scale; SD, standard deviation; TIA, transient ischemic attack; TOAST, Trial of Org 10172 in Acute Stroke Treatment.

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Ischemic stroke, ISTH major bleeding, and hemorrhagic stroke outcomes in Chinese participants in East Asia

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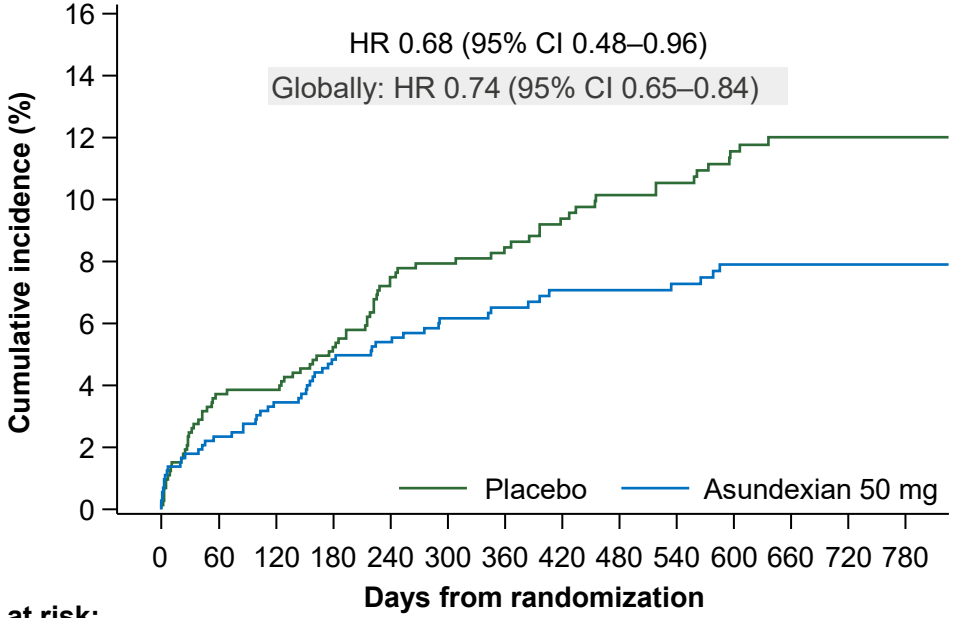
Outcome	Asundexian 50 mg N=721 n/N (%)	Placebo N=720 n/N (%)	csHR (95% CI)†	Log-rank p value‡
Ischemic stroke§	53/725 (7.3)	78/726 (10.7)	0.68 (0.48–0.96)	0.03
ISTH major bleeding	15/721 (2.1)	16/720 (2.2)	0.96 (0.47–1.93)	0.90
Hemorrhagic stroke	5/721 (0.7)	4/720 (0.6)	1.31 (0.35–4.88)	0.69

†csHRs are estimated from stratified Cox PH model (stratified by baseline intention of DAPT).
‡P values are obtained from stratified log-rank test (stratified by baseline intention of DAPT).
§Ischemic stroke here includes undetermined stroke.
CI, confidence interval; csHR, cause-specific hazard ratio; DAPT, dual antiplatelet therapy; ISTH, International Society on Thrombosis and Haemostasis.

Efficacy outcome (ischemic stroke)

Ischemic stroke in Chinese participants in East Asia



No. at risk:

Placebo	726	695	640	501	460	413	184
Asundexian 50 mg	725	691	643	515	463	420	180

CI, confidence interval; HR, hazard ratio.

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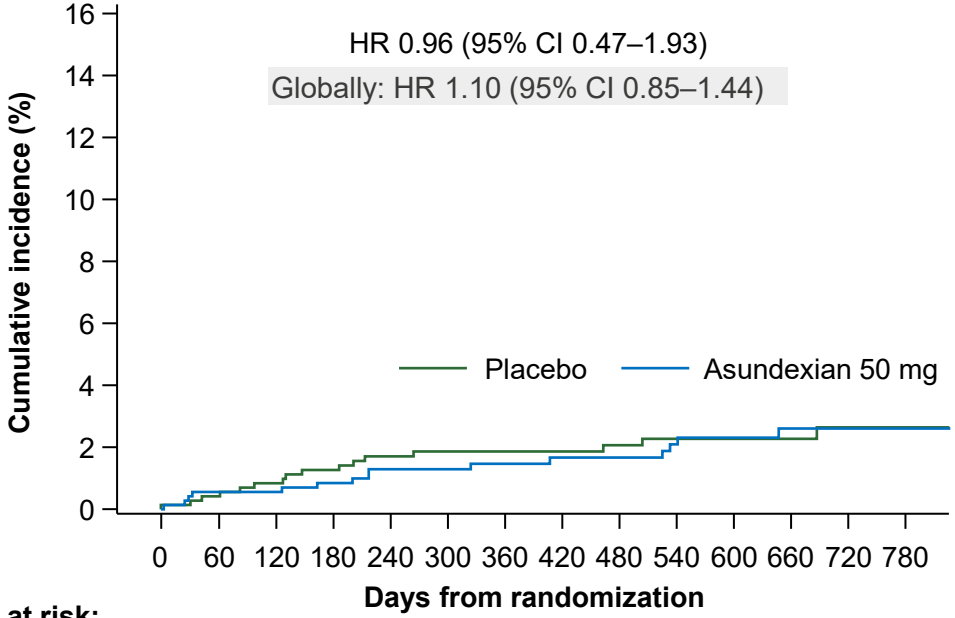
Safety outcome (ISTH major bleeding)

ISTH major bleeding in Chinese participants in East Asia



No. at risk:

Placebo	720	616	553	432	396	355	159
Asundexian 50 mg	721	609	539	427	379	340	144

CI, confidence interval; HR, hazard ratio.
ISTH, International Society on Thrombosis and Haemostasis.

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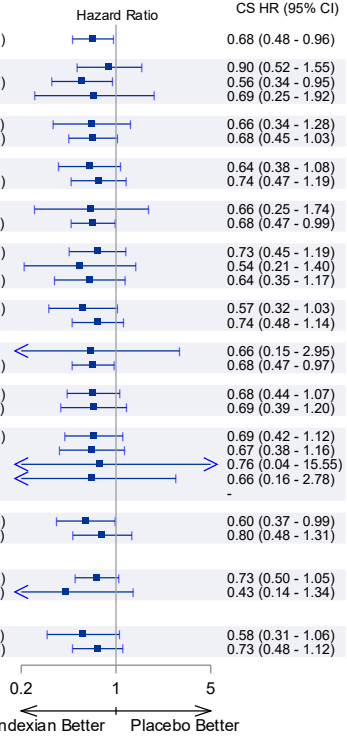
Subgroup analyses for ischemic stroke restricted to Chinese participants

Group	Asundexian	Placebo	CS HR (95% CI)
Overall Ischemic Stroke	53/725 (7.3%)	78/726 (10.7%)	0.68 (0.48 - 0.96)
Age			
<65 years	25/403 (6.2%)	26/373 (7.0%)	0.90 (0.52 - 1.55)
65 to 75 years	22/255 (8.6%)	42/282 (14.9%)	0.56 (0.34 - 0.95)
>75 years	6/67 (9.0%)	10/71 (14.1%)	0.69 (0.25 - 1.92)
Sex			
Female	15/199 (7.5%)	22/200 (11.0%)	0.66 (0.34 - 1.28)
Male	38/526 (7.2%)	56/526 (10.6%)	0.68 (0.45 - 1.03)
History of stroke or TIA before index event			
No	23/485 (4.7%)	35/471 (7.4%)	0.64 (0.38 - 1.08)
Yes	30/240 (12.5%)	43/255 (16.9%)	0.74 (0.47 - 1.19)
Hypertension before randomization			
No	7/150 (4.7%)	10/142 (7.0%)	0.66 (0.25 - 1.74)
Yes	46/575 (8.0%)	68/584 (11.6%)	0.68 (0.47 - 0.99)
Smoking			
Never	29/375 (7.7%)	39/374 (10.4%)	0.73 (0.45 - 1.19)
Former	7/89 (7.9%)	11/77 (14.3%)	0.54 (0.21 - 1.40)
Current	17/261 (6.5%)	28/275 (10.2%)	0.64 (0.35 - 1.17)
Time from index event to randomization			
<=48 hours	19/253 (7.5%)	28/215 (13.0%)	0.57 (0.32 - 1.03)
>48 hours	34/472 (7.2%)	50/511 (9.8%)	0.74 (0.48 - 1.14)
Vascular imaging evidence of atherosclerosis			
No	3/50 (6.0%)	4/47 (8.5%)	0.66 (0.15 - 2.95)
Yes	50/675 (7.4%)	74/679 (10.9%)	0.68 (0.47 - 0.97)
Acute nonlacunar infarct on imaging of head			
No	32/456 (7.0%)	48/464 (10.3%)	0.68 (0.44 - 1.07)
Yes	21/269 (7.8%)	30/262 (11.5%)	0.69 (0.39 - 1.20)
Stroke subtype			
Large-artery atherosclerosis	28/321 (8.7%)	37/289 (12.8%)	0.69 (0.42 - 1.12)
Small-vessel occlusion (lacune)	21/334 (6.3%)	32/343 (9.3%)	0.67 (0.38 - 1.16)
Stroke of other determined etiology	1/7 (14.3%)	1/8 (12.5%)	0.76 (0.04 - 15.55)
Stroke of undetermined etiology	3/49 (6.1%)	5/57 (8.8%)	0.66 (0.16 - 2.78)
Cardioembolism	0/1 (0.0%)	0/1 (0.0%)	-
NIHSS score for index stroke at randomization			
<=3	25/412 (6.1%)	41/404 (10.1%)	0.60 (0.37 - 0.99)
>=4	28/300 (9.3%)	34/294 (11.6%)	0.80 (0.48 - 1.31)
Intravenous thrombolysis or endovascular therapy for index stroke			
No	49/621 (7.9%)	64/591 (10.8%)	0.73 (0.50 - 1.05)
Yes	4/91 (4.4%)	11/107 (10.3%)	0.43 (0.14 - 1.34)
Planned dual antiplatelet therapy with aspirin and a P2Y12 inhibitor			
No	16/231 (6.9%)	28/235 (11.9%)	0.58 (0.31 - 1.06)
Yes	37/494 (7.5%)	50/491 (10.2%)	0.73 (0.48 - 1.12)



CI, confidence interval; CS HR, cause-specific hazard ratio; NIHSS, National Institutes of Health Stroke Scale; P2Y12, purinergic receptor Y12.

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Conclusion

- Chinese participants were younger, more likely to be male, and have previous stroke, diabetes, current tobacco use, and small vessel occlusion subtype index strokes, when compared descriptively with the overall OCEANIC-STROKE population
- Chinese participants were less likely to be treated with IVT or EVT
- Among Chinese participants with acute noncardioembolic ischemic stroke or high-risk TIA, asundexian added to antiplatelet therapy reduced ischemic stroke occurrence compared with antiplatelet therapy alone, **without increasing the risk of ISTH major bleeding**
- Treatment effects were generally consistent across prespecified subgroups

EVT, endovascular thrombectomy; IVT, intravenous thrombolysis; ISTH, International Society on Thrombosis and Haemostasis; TIA, transient ischemic attack.

Acknowledgments

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