DUAL ANTIPLATELET THERAPY (DAPT) DURING THE FIRST 90 DAYS POST-RANDOMISATION IN OCEANIC-STROKE: PARTICIPANT CHARACTERISTICS AND INTERACTION WITH ASUNDEXIAN

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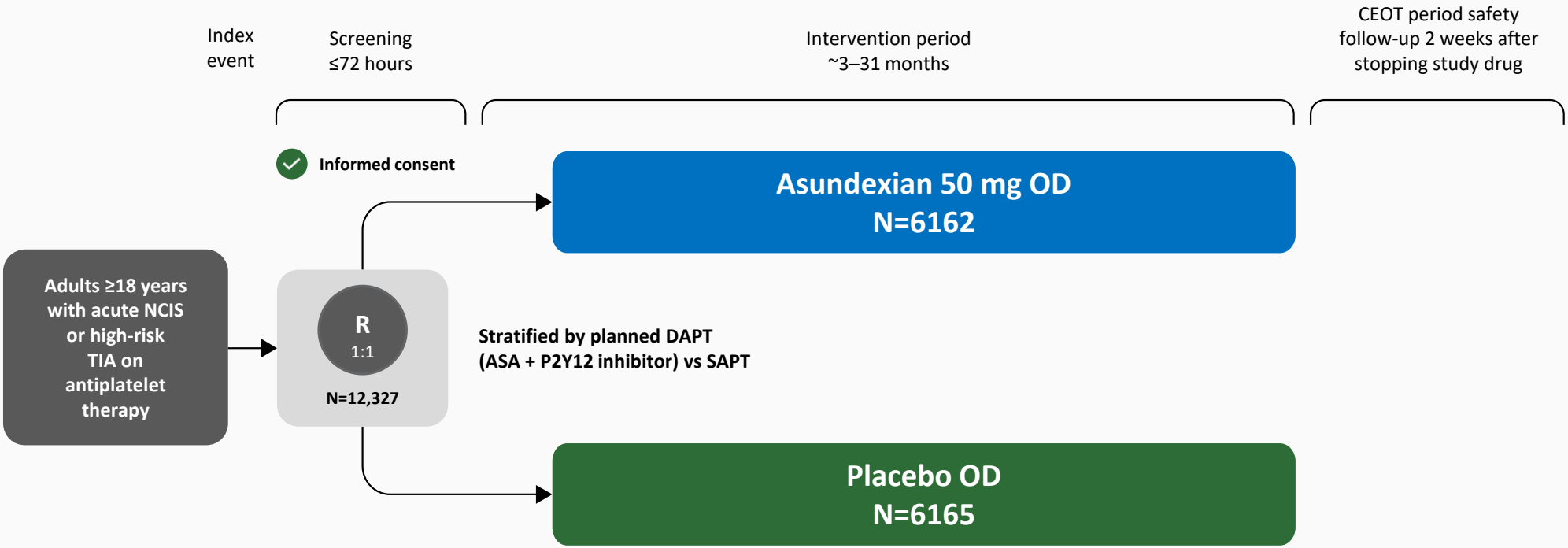
Disclosures

- M.S. declares consulting for Bayer, Regeneron and Anthos; research funding for the current study from Bayer paid to his institution; research funding from BMS and Janssen; serving on an endpoint review committee for AtriCure

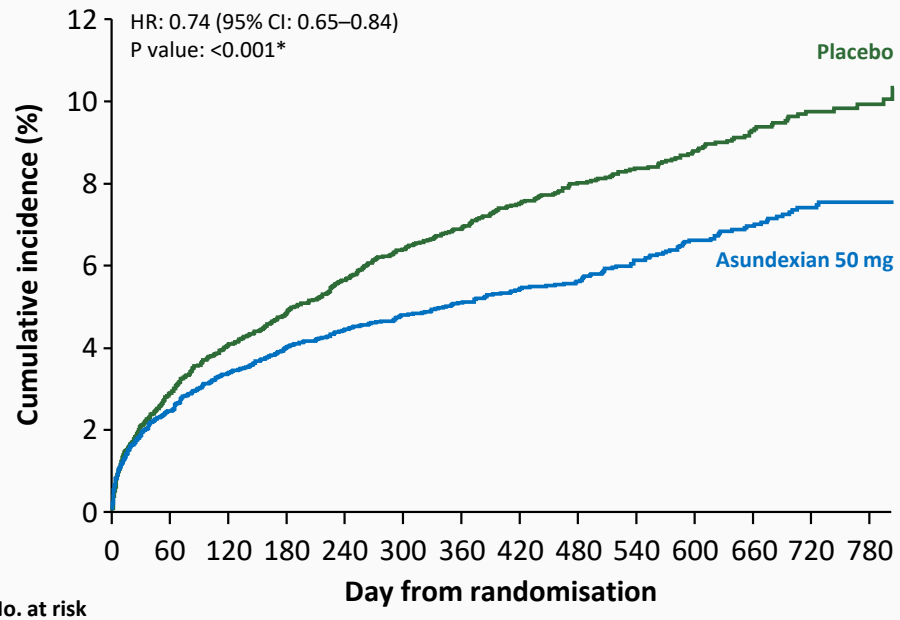
OCEANIC-STROKE: Study Design



ASA, acetylsalicylic acid; CEOT, common end of treatment; DAPT, dual antiplatelet therapy; NCIS, non-cardioembolic ischaemic stroke; OD, once daily; P2Y12, purinergic receptor Y12; R, randomised; SAPT, single antiplatelet therapy; TIA, transient ischaemic attack.

OCEANIC-STROKE Primary Efficacy and Safety Endpoints

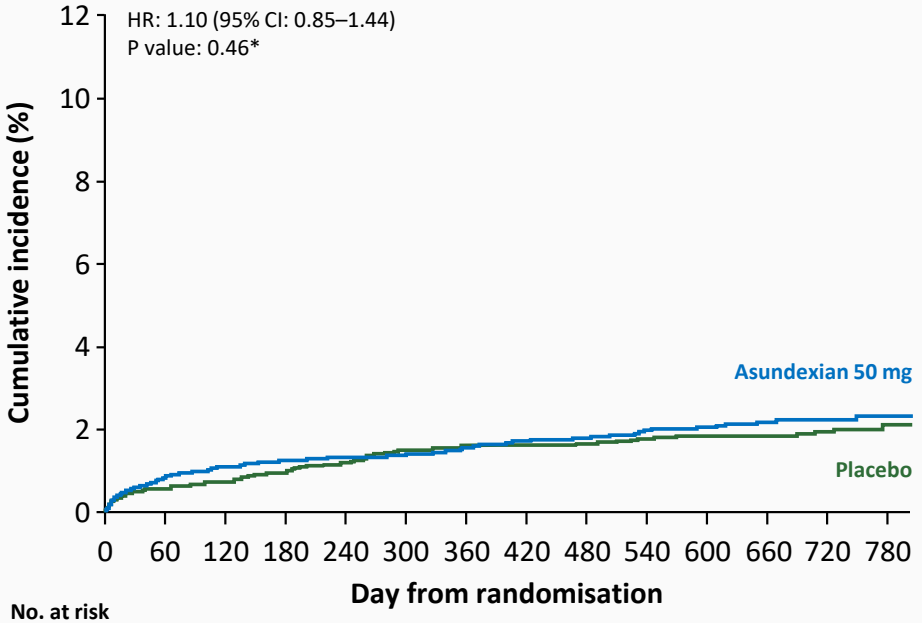
Cumulative Incidence of Ischaemic Stroke†



No. at risk

Placebo	6165	5949	5853	5754	5370	4840	4406	3990	3497	3070	2564	1961	1410	792
Asundexian 50 mg	6162	5958	5859	5763	5384	4876	4463	4033	3543	3101	2588	2004	1428	810

Cumulative Incidence of ISTH Major Bleeding‡



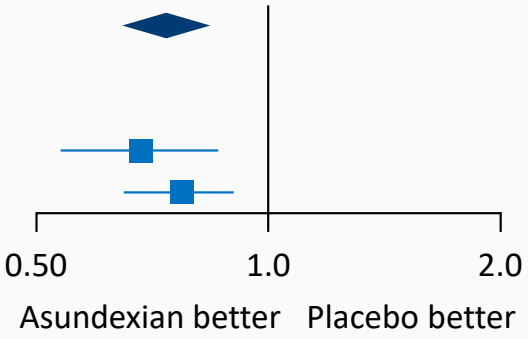
No. at risk

Placebo	6130	5391	5021	4833	4415	3944	3572	3165	2775	2441	2026	1549	1121	618
Asundexian 50 mg	6124	5354	4968	4807	4366	3900	3547	3104	2699	2374	1943	1508	1082	613

*P value is obtained from stratified log-rank test (stratified by baseline intention of DAPT). csHR and 95% CI are provided here.
†ARR at 1 year was 1.9%, with a number NNT of 54; and at 2 years ARR was 2.2%, with an NNT of 46. Cumulative incidence curves are estimated by Aalen–Johansen method. Plot truncated at Day 820; based on the full analysis set.
‡Cumulative incidence curves are estimated by Aalen–Johansen method, truncated at Day 820.
ARR, absolute risk reduction; CI, confidence interval; csHR, cause-specific hazard ratio; DAPT, dual antiplatelet therapy; HR, hazard ratio; ISTH, International Society on Thrombosis and Haemostasis; NNT, needed to treat.

OCEANIC-STROKE Primary Efficacy Endpoint: DAPT Subgroup

	Asundexian n/N(%)	Placebo n/N(%)	Cause-specific hazard ratio (95% CI)
Overall ischaemic stroke	384/6162 (6.2)	518/6165 (8.4)	0.74 (0.65–0.84)
Planned DAPT with aspirin and a P2Y12 inhibitor			
No	119/2303 (5.2)	174/2312 (7.5)	0.68 (0.54–0.86)
Yes	265/3859 (6.9)	344/3853 (8.9)	0.77 (0.65–0.90)



CI, confidence interval; DAPT, dual antiplatelet therapy; P2Y12, purinergic receptor Y12.

Objective and Methods

- Antiplatelet use and outcomes **within 90 days of randomisation** were assessed
  - Post-hoc, exploratory analysis
- Objective: Examine safety and efficacy outcomes for interaction with DAPT use
  - Participants receiving DAPT were those who received DAPT (ASA + P2Y12 inhibitor) for at least 1 day; separately as a time-varying covariate
- Analytic approach:
  - csHRs using Cox proportional hazard models were created for the primary efficacy and safety outcomes of ischaemic stroke and ISTH major bleeding and tested for interaction with receiving DAPT
  - csHRs considering DAPT as a time-varying covariate to determine an interaction with receiving DAPT within the 90-day period
  - Similar csHRs were calculated for pre-specified secondary efficacy and safety outcomes

ASA, acetylsalicylic acid; csHR, cause-specific hazard ratio; DAPT, dual antiplatelet therapy; ISTH, International Society on Thrombosis and Haemostasis; P2Y12, purinergic receptor Y12.

Antiplatelet Therapy Received (First 90 Days)

Antiplatelet therapy received (90 days post randomisation)	Overall N=12327	Planned DAPT (yes) N=7712	Planned DAPT (no) N=4615
Received any DAPT†			
N (%)	7909 (64.2)	6840 (88.7)	1069 (23.2)
Received only SAPT‡			
N (%)	4122 (33.4)	739 (9.6)	3383 (73.3)
Received other combinations			
N (%)	125 (1.0)	40 (0.5)	85 (1.8)
Received no APT§			
N (%)	171 (1.4)	93 (1.2)	78 (1.7)

†Received any DAPT is defined as a patient receiving ASA + a P2Y12 inhibitor (clopidogrel, prasugrel, ticagrelor) on at least 1 day within 90 days after randomisation. ‡Received only SAPT is defined as receiving any one of the six specified antiplatelets only (ASA, cilostazol, clopidogrel, dipyridamole, prasugrel, ticagrelor) on at least 1 day within 90 days after randomisation. §No APT treatment is defined as receiving none of the six specified antiplatelets (ASA, cilostazol, clopidogrel, dipyridamole, prasugrel, ticagrelor) at any day during the 90 days post randomisation.
APT, antiplatelet therapy; ASA, acetylsalicylic acid; DAPT, dual antiplatelet therapy; P2Y12, purinergic receptor Y12; SAPT, single antiplatelet therapy.

Baseline Characteristics by Received DAPT (First 90 days)

Characteristics	Received DAPT Yes	Received DAPT No
No. of participant	7909	4418
Mean age, years (SD)	67.5 (10.8)	67.7 (10.9)
Female sex, n (%)	2413 (30.5)	1697 (38.4)
Race, n (%)		
White	4890 (61.8)	3293 (74.5)
Black	173 (2.2)	109 (2.5)
Asian	2596 (32.8)	867 (19.6)
Other	250 (3.2)	149 (3.4)
Index event, n (%)	7908 (100.0)	4417 (100.0)
Ischaemic stroke[†]	7441 (94.1)	4236 (95.9)
TIA[†]	467 (5.9)	181 (4.1)
Stroke subtype, TOAST classification, n (%)[‡]		
Large-artery atherosclerosis	3484 (46.8)	1512 (35.7)
Small-vessel occlusion (lacune)	1777 (23.9)	862 (20.4)
Stroke of other determined aetiology	195 (2.6)	154 (3.6)
Stroke of undetermined aetiology	1889 (25.4)	1607 (37.9)
Cardioembolism	95 (1.3)	101 (2.4)

[†]% of index event. [‡]For participants with index event of ischaemic stroke only.
DAPT, dual antiplatelet therapy; SD, standard deviation; TIA, transient ischaemic attack.

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†% of index event. ‡For participants with index event of ischaemic stroke only.
DAPT, dual antiplatelet therapy; SD, standard deviation; TIA, transient ischaemic attack.

Baseline Characteristics by Received DAPT (First 90 days)

Characteristics	Received DAPT Yes	Received DAPT No
IVT and/or EVT, n (%)†	1579 (21.2)	1622 (38.3)
Intravenous thrombolysis only	1125 (15.1)	1189 (28.1)
Endovascular therapy only	219 (2.9)	152 (3.6)
Intravenous thrombolysis and endovascular therapy	235 (3.2)	281 (6.6)
NIHSS at randomisation, median (IQR)†	2.0 (1.0–4.0)	2.0 (1.0–4.0)
Entry criterion, n (%)		
Medical history of atherosclerosis	2723 (34.4)	1267 (28.7)
Vascular imaging evidence of atherosclerosis	7330 (92.7)	3919 (88.7)
Brain imaging demonstrating acute non-lacunar infarct	3692 (46.7)	2304 (52.2)

†For participants with index event of ischaemic stroke only.
DAPT, dual antiplatelet therapy; EVT, endovascular thrombectomy; IQR, interquartile range; IVT, intravenous thrombolysis; NIHSS, National Institutes of Health Stroke Scale.

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†For participants with index event of ischaemic stroke only.
DAPT, dual antiplatelet therapy; EVT, endovascular thrombectomy; IQR, interquartile range; IVT, intravenous thrombolysis; NIHSS, National Institutes of Health Stroke Scale.

DAPT Duration and Type (First 90 Days)

	Overall N=12327	Asundexian N=6162	Placebo N=6165
DAPT			
N (%)	7909 (64.2)	3939 (63.9)	3970 (64.4)
Median duration in days (IQR)	28.0 (20.0–90.0)	28.0 (20.0–90.0)	28.0 (20.0–90.0)
ASA + clopidogrel			
N (%)	7576 (95.8)	3789 (96.2)	3787 (95.4)
ASA + prasugrel			
N (%)	259 (3.3)	119 (3.0)	140 (3.5)
ASA + ticagrelor			
N (%)	243 (3.1)	111 (2.8)	132 (3.3)

Duration was calculated as the number of days the participant is on DAPT (ASA + P2Y12 inhibitors: clopidogrel, prasugrel, ticagrelor), at any time up to 90 days post randomisation. Non-consecutive periods of a combination were summed. Participant could contribute to more than one group.
ASA, acetylsalicylic acid; DAPT, dual antiplatelet therapy; IQR, interquartile range; P2Y12, purinergic receptor Y12.

No DAPT Received (First 90 Days)

n (%)	Overall N=4418	Asundexian N=2223	Placebo N=2195
SAPT[†]	4122 (93.3)	2068 (93.0)	2054 (93.6)
ASA	3379 (76.5)	1698 (76.4)	1681 (76.6)
Clopidogrel	835 (18.9)	413 (18.6)	422 (19.2)
Cilostazol	11 (0.3)	4 (0.2)	7 (0.3)
Prasugrel	25 (0.6)	16 (0.7)	9 (0.4)
Ticagrelor	13 (0.3)	7 (0.3)	6 (0.3)
Dipyridamole	1 (0.0)	0 (0.0)	1 (0.1)
Other combinations[‡]	125 (2.8)	72 (3.2)	53 (2.4)
No APT treatment[§]	171 (3.9)	83 (3.7)	88 (4.0)

[†]The SAPT groups are not mutually exclusive. A participant may be included in the ASA group and another APT group at different time points. For example, a participant may receive ASA only on Day 1 and clopidogrel only from Day 2 through Day 90. [‡]Combinations other than ASA + one of clopidogrel, ticagrelor or prasugrel. [§]No APT treatment is defined as receiving none of the six specified antiplatelets (ASA, cilostazol, clopidogrel, dipyridamole, prasugrel, ticagrelor) at any day during the 90 days post randomisation.
APT, antiplatelet therapy; ASA, acetylsalicylic acid; DAPT, dual antiplatelet therapy; SAPT, single antiplatelet therapy.

Efficacy Outcomes (First 90 Days): Received DAPT, Treatment Interaction

Outcomes	Asundexian N=6162	Placebo N=6165	Cause-specific HR† (95% CI)	P for interaction
Ischaemic stroke‡				0.26
DAPT No	35/2223 (1.6%)	51/2195 (2.3%)	0.68 (0.44–1.04)	
DAPT Yes	148/3939 (3.8%)	167/3970 (4.2%)	0.89 (0.72–1.12)	
All stroke				0.28
DAPT No	36/2223 (1.6%)	52/2195 (2.4%)	0.68 (0.45–1.04)	
DAPT Yes	154/3939 (3.9%)	175/3970 (4.4%)	0.89 (0.71–1.10)	
Composite: CV death§, MI or stroke				0.52
DAPT No	53/2223 (2.4%)	66/2195 (3.0%)	0.79 (0.55–1.13)	
DAPT Yes	181/3939 (4.6%)	201/3970 (5.1%)	0.91 (0.74–1.11)	
Composite: All-cause mortality, MI or stroke				0.60
DAPT No	63/2223 (2.8%)	73/2195 (3.3%)	0.85 (0.61–1.19)	
DAPT Yes	196/3939 (5.0%)	209/3970 (5.3%)	0.95 (0.78–1.15)	
Disabling or fatal stroke‖				0.43
DAPT No	14/2223 (0.6%)	23/2195 (1.0%)	0.60 (0.31–1.17)	
DAPT Yes	51/3939 (1.3%)	63/3970 (1.6%)	0.82 (0.56–1.18)	

†Cause-specific HRs for each sub-group estimated from stratified Cox proportional hazards models, stratified by planned DAPT treatment. ‡Ischaemic stroke here includes undetermined stroke. §CV death here includes undetermined death. ‖A disabling stroke is defined as a stroke of any type during the trial associated with a mRS of ≥3 at 90 days after the stroke or an increase of one point if the last available mRS before the recurrent stroke event was ≥3.
CI, confidence interval; CV, cardiovascular; DAPT, dual antiplatelet therapy; HR, hazard ratio; MI, myocardial infarction; mRS, modified Rankin Scale.

Safety Outcomes (First 90 Days): Received DAPT, Treatment Interaction

Outcomes	Asundexian N=6124	Placebo N=6130	Cause-specific HR† (95% CI)	P for interaction
ISTH major bleeding				0.33
DAPT No	17/2203 (0.8%)	8/2177 (0.4%)	2.11 (0.91–4.89)	
DAPT Yes	44/3921 (1.1%)	34/3953 (0.9%)	1.31 (0.84–2.05)	
ISTH major or CRNM bleeding				0.51
DAPT No	49/2203 (2.2%)	34/2177 (1.6%)	1.43 (0.92–2.21)	
DAPT Yes	130/3921 (3.3%)	109/3953 (2.8%)	1.21 (0.93–1.56)	
Minor bleeding				0.71
DAPT No	69/2203 (3.1%)	69/2177 (3.2%)	0.99 (0.71–1.38)	
DAPT Yes	196/3921 (5.0%)	216/3953 (5.5%)	0.92 (0.76–1.11)	

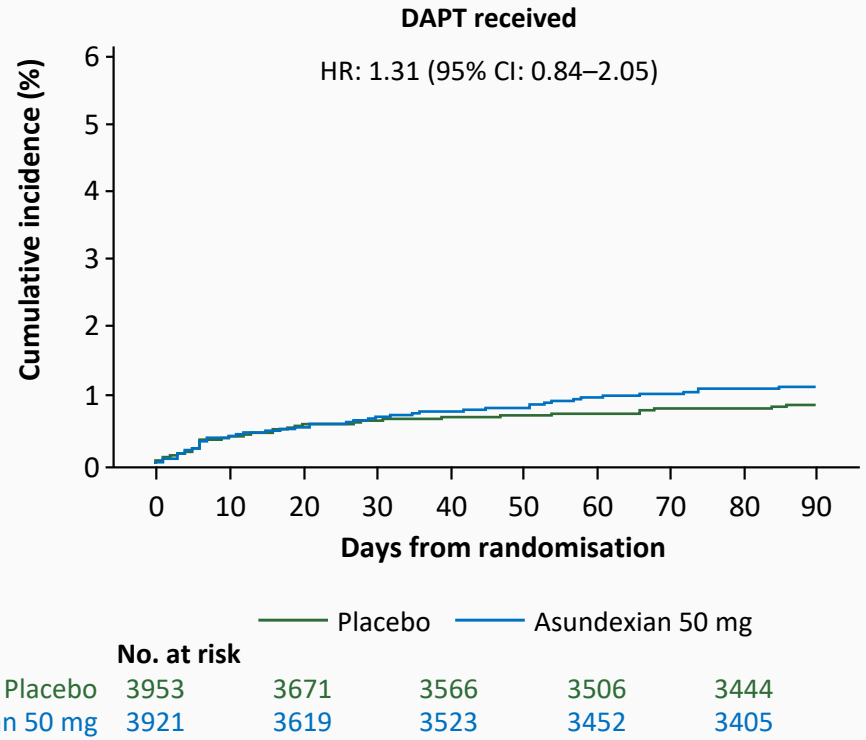
†Cause-specific HRs for each sub-group estimated from stratified Cox proportional hazards models, stratified by planned DAPT treatment.
CI, confidence interval; CRNM, clinically relevant non-major; DAPT, dual antiplatelet therapy; HR, hazard ratio;
ISTH, International Society on Thrombosis and Haemostasis.

Safety Outcomes (First 90 Days): Received DAPT, Treatment Interaction

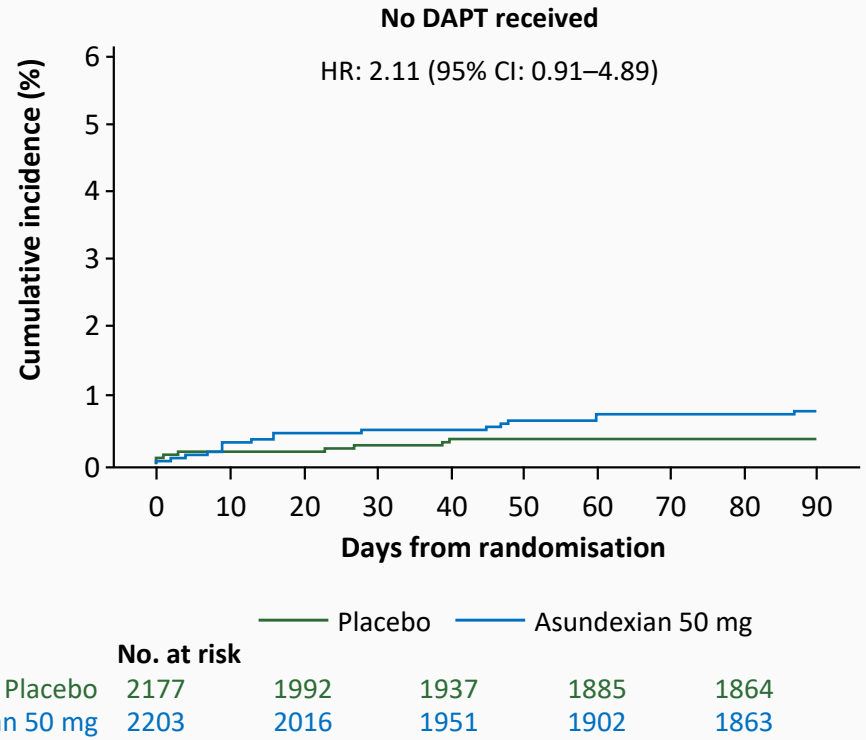
Outcomes	Asundexian N=6124	Placebo N=6130	Cause-specific HR† (95% CI)	P for interaction
Symptomatic intracranial haemorrhage				0.47
DAPT No	6/2203 (0.3%)	4/2177 (0.2%)	1.48 (0.42–5.26)	
DAPT Yes	11/3921 (0.3%)	13/3953 (0.3%)	0.86 (0.39–1.92)	
Haemorrhagic stroke				N/A
DAPT No	1/2203 (0.0%)	1/2177 (0.0%)	N/A	
DAPT Yes	5/3921 (0.1%)	7/3953 (0.2%)	0.73 (0.23–2.30)	
Gastrointestinal bleeding				0.78
DAPT No	24/2203 (1.1%)	14/2177 (0.6%)	1.70 (0.88–3.28)	
DAPT Yes	86/3921 (2.2%)	57/3953 (1.4%)	1.53 (1.10–2.14)	

†Cause-specific HRs for each sub-group estimated from stratified Cox proportional hazards models, stratified by planned DAPT treatment.
CI, confidence interval; DAPT, dual antiplatelet therapy; HR, hazard ratio; N/A, not available.

Cumulative Incidence of ISTH Major Bleeding by DAPT Received Status



No. at risk					
Placebo	3953	3671	3566	3506	3444
Asundexian 50 mg	3921	3619	3523	3452	3405



No. at risk					
Placebo	2177	1992	1937	1885	1864
Asundexian 50 mg	2203	2016	1951	1902	1863

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

Efficacy Outcomes (First 90 Days): Time Varying Analysis of Received DAPT, Treatment Interaction

Outcomes	Asundexian (N=6162) Event/pt years (Rate per 100 pt-years)	Placebo (N=6165) Event/pt years (Rate per 100 pt-years)	Cause-specific HR[†] (95% CI)	P for interaction
Ischemic stroke[‡]				0.20
DAPT No	82/995 (8.2)	111/993 (11.2)	0.73 (0.55–0.98)	
DAPT Yes	101/482 (20.9)	107/484 (22.1)	0.95 (0.73–1.25)	
All stroke				0.14
DAPT No	84/994 (8.5)	116/992 (11.7)	0.72 (0.54–0.95)	
DAPT Yes	106/482 (22.0)	111/484 (22.9)	0.96 (0.74–1.26)	
Composite: CV death[§], MI or stroke				0.26
DAPT No	110/993 (11.1)	138/991 (13.9)	0.79 (0.62–1.02)	
DAPT Yes	124/481 (25.8)	129/482 (26.8)	0.97 (0.76–1.24)	
Composite: All-cause mortality, MI or stroke				0.44
DAPT No	129/993 (13.0)	149/991 (15.0)	0.86 (0.68–1.09)	
DAPT Yes	130/481 (27.0)	133/482 (27.6)	0.98 (0.77–1.25)	
Disabling or fatal stroke[‖]				0.67
DAPT No	29/1004 (2.9)	41/1003 (4.1)	0.70 (0.44–1.13)	
DAPT Yes	36/491 (7.3)	45/494 (9.1)	0.81 (0.52–1.25)	

[†]Cause-specific HR for each subgroup was estimated from a stratified Cox proportional hazard model that included received DAPT as a time-varying covariate, treatment (asundexian) and received DAPT*treatment (interaction term). [‡]Ischaemic stroke here includes undetermined stroke. [§]CV death here includes undetermined death. [‖]A disabling stroke is defined as a stroke of any type during the trial associated with a mRS of ≥3 at 90 days after the stroke or an increase of 1 point if the last available mRS before the recurrent stroke event was ≥3.

CI, confidence interval; CV, cardiovascular; DAPT, dual antiplatelet therapy; HR, hazard ratio; MI, myocardial infarction; mRS, modified Rankin Scale; Pt, patient.

Safety Outcomes: Time Varying Analysis of Received DAPT, Treatment Interaction

Outcomes	Asundexian (N=6124) Event/pt years (Rate per 100 pt-years)	Placebo (N=6130) Event/pt years (Rate per 100 pt-years)	Cause-specific HR† (95% CI)	P for interaction
ISTH major bleeding				0.83
DAPT No	31/896 (3.5)	22/898 (2.5)	1.40 (0.81–2.42)	
DAPT Yes	30/458 (6.6)	20/463 (4.3)	1.52 (0.87–2.68)	
ISTH major or CRNM bleeding				0.37
DAPT No	95/883 (10.8)	68/887 (7.7)	1.39 (1.02–1.90)	
DAPT Yes	84/454 (18.5)	75/460 (16.3)	1.14 (0.83–1.56)	
Minor bleeding				0.94
DAPT No	126/868 (14.5)	133/867 (15.3)	0.94 (0.74–1.20)	
DAPT Yes	139/446 (31.2)	152/450 (33.7)	0.93 (0.74–1.17)	

†Cause-specific HR for each subgroup was estimated from a stratified Cox proportional hazard model that included received DAPT as a time-varying covariate, treatment (asundexian) and received DAPT*treatment (interaction term).
CI, confidence interval; CRNM, clinically relevant non-major; DAPT, dual antiplatelet therapy; HR, hazard ratio; ISTH, International Society on Thrombosis and Haemostasis; Pt, patient.

Safety Outcomes: Time Varying Analysis of Received DAPT, Treatment Interaction

Outcomes	Asundexian (N=6124) Event/pt years (Rate per 100 pt-years)	Placebo (N=6130) Event/pt years (Rate per 100 pt-years)	Cause-specific HR[†] (95% CI)	P for interaction
Symptomatic intracranial haemorrhage				0.73
DAPT No	12/899 (1.3)	11/899 (1.2)	1.08 (0.48–2.46)	
DAPT Yes	5/459 (1.1)	6/464 (1.3)	0.85 (0.26–2.77)	
Haemorrhagic stroke				0.99
DAPT No	3/899 (0.3)	4/900 (0.4)	0.75 (0.17–3.34)	
DAPT Yes	3/459 (0.7)	4/464 (0.9)	0.76 (0.17–3.40)	
Gastrointestinal bleeding				0.15
DAPT No	56/888 (6.3)	28/892 (3.1)	1.99 (1.27–3.14)	
DAPT Yes	54/456 (11.9)	43/463 (9.3)	1.28 (0.86–1.91)	

[†]Cause-specific HR for each subgroup was estimated from a stratified Cox proportional hazard model that included received DAPT as a time-varying covariate, treatment (asundexian) and received DAPT*treatment (interaction term).
CI, confidence interval; DAPT, dual antiplatelet therapy; HR, hazard ratio; Pt, patient.

Conclusions

- The OCEANIC-STROKE trial enrolled a NCIS and high-risk TIA population, two-thirds of whom were treated with DAPT in the first 90 days
- Patients receiving DAPT were more likely to be Asian, had more large-artery atherosclerosis as index stroke subtype and had a higher risk of stroke and ISTH major bleeding compared to those not receiving DAPT
- The efficacy and safety of asundexian in the first 90 days were similar in those treated with or without DAPT
  - Modelling DAPT as a time-varying covariate showed no significant interaction between the effect of asundexian and antiplatelet treatment for the outcomes of ischaemic stroke, ISTH major bleeding as well as the secondary efficacy and safety outcomes

DAPT, dual antiplatelet therapy; ISTH, International Society on Thrombosis and Haemostasis; NCIS, non-cardioembolic ischaemic stroke; TIA, transient ischaemic attack.

Conclusions

- Limitations
  - Assignment to DAPT was not randomised and outcomes may be confounded by indication
  - Participants who received DAPT differed in baseline characteristics from those who did not
  - The current analysis was limited to the first 90 days post randomisation reflecting the use of DAPT in patients with stroke or TIA
- The efficacy and safety of asundexian in the first 90 days were similar in those treated with or without DAPT

DAPT, dual antiplatelet therapy; TIA, transient ischaemic attack.

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