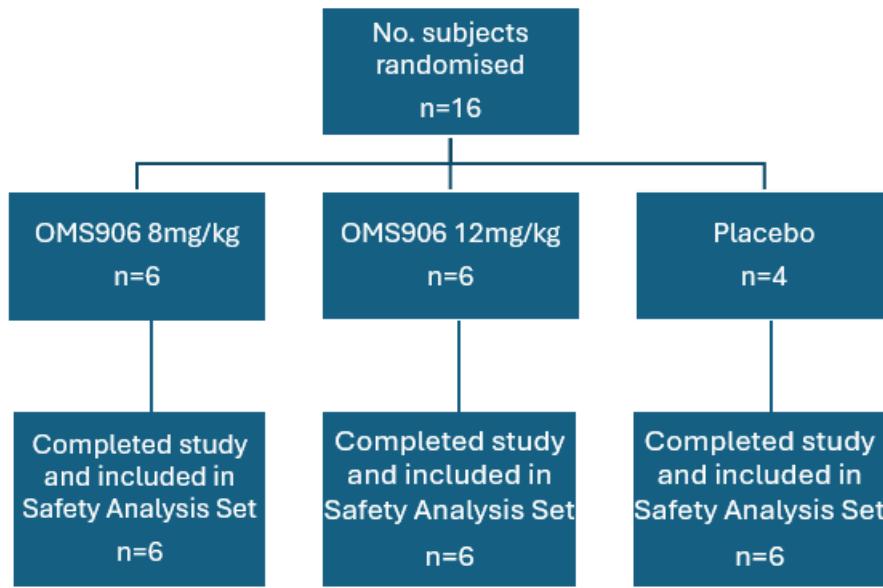


Participant Flow



Baseline Characteristics

Table 1: Baseline Characteristics

	OMS906 8 mg/kg N=6	OMS906 12 mg/kg N=6	Pooled Placebo N=4	Overall N=16
Age at Consent (years)				
Mean	36.3	32.3	28.3	32.8
SD	13.09	12.82	12.53	12.41
Minimum	23	20	21	20
Median	31.5	26.0	22.5	27.0
Maximum	58	51	47	58
Sex				
Female, n (%)	2 (33.3)	2 (33.3)	2 (50.0)	6 (37.5)
Male, n (%)	4 (66.7)	4 (66.7)	2 (50.0)	10 (62.5)
Ethnicity				
Not Hispanic or Latino, n (%)	6 (100.0)	6 (100.0)	4 (100.0)	16 (100.0)
Race				
Asian, n (%)	1 (16.7)	2 (33.3)	0	3 (18.8)
Black or African American, n (%)	0	1 (16.7)	1 (25.0)	2 (12.5)
White, n (%)	5 (83.3)	3 (50.0)	3 (75.0)	11 (68.8)
Height (m)				
Mean	1.705	1.702	1.705	1.704
SD	0.0846	0.0813	0.1028	0.0819
Minimum	1.60	1.61	1.59	1.59
Median	1.730	1.690	1.695	1.695
Maximum	1.78	1.79	1.84	1.84
Weight (kg)				
Mean	72.30	70.57	69.28	70.89
SD	11.607	14.798	16.911	13.290

	OMS906 8 mg/kg N=6	OMS906 12 mg/kg N=6	Pooled Placebo N=4	Overall N=16
Minimum	59.6	54.0	52.8	52.8
Median	71.45	69.20	65.95	68.45
Maximum	85.8	88.3	92.4	92.4
Body Mass Index (kg/m ²)				
Mean	24.85	24.12	23.53	24.24
SD	3.307	3.093	2.944	2.977
Minimum	21.3	20.1	20.9	20.1
Median	25.05	23.45	22.95	23.85
Maximum	29.2	27.8	27.3	29.2

Abbreviations: kg = kilograms; m = metre; N = number of subjects who received at least one dose of OMS906 at the stated dose or placebo; n = number of subjects for each parameter/row who received at least one dose of OMS906 at the stated dose or placebo; SD = standard deviation.

% = n/N*100.

Outcome Measures

Table 2: Summary of Treatment-emergent Adverse Events (Safety Analysis Set)

Number of Subjects With:	OMS906 8 mg/kg N=6 n (%) [E]	OMS906 12 mg/kg N=6 n (%) [E]	Pooled Placebo N=4 n (%) [E]	Overall N=16 n (%) [E]
Any TEAE	4 (66.7) [9]	2 (33.3) [4]	3 (75.0) [8]	9 (56.3) [21]
Any serious TEAE	0	0	0	0
Any TEAE leading to discontinuation of treatment	0	0	0	0
TEAE leading to deaths	0	0	0	0
Severity of TEAEs ^a				
Mild	1 (16.7) [1]	0	1 (25.0) [1]	2 (12.5) [2]
Moderate	3 (50.0) [5]	2 (33.3) [4]	2 (50.0) [3]	7 (43.8) [12]
Severe	0	0	0	0
Causality of TEAEs ^b				
Not related	1 (16.7) [1]	1 (16.7) [2]	1 (25.0) [1]	3 (18.8) [4]
Unlikely related	3 (50.0) [4]	1 (16.7) [2]	2 (50.0) [4]	6 (37.5) [10]
Possibly related	0	0	0	0
Probably related	0	0	0	0
Related ^c	0	0	0	0

Abbreviations: E = number of events; N = number of subjects who received at least one dose of OMS906 at the stated dose or placebo; n = number of subjects with events; TEAE = treatment-emergent adverse event (defined as any adverse event that began or worsened after administration of the study medication).

% = n/N*100.

a Subjects are counted once per TEAE for the worst severity only. Events are counted for the worst severity.

b Subjects are counted once per TEAE for the worst causality only. Events are counted for the worst causality.

c Related included possibly and probably related.

There were no clinically significant abnormal results for any vital signs parameters including systolic blood pressure, diastolic blood pressure, pulse rate, respiratory rate, and body temperature.

No clinically significant abnormal 12-lead ECG results were reported.

The majority of subjects had laboratory test results for clinical haematology and clinical chemistry within normal range at baseline and during the treatment period (through to Day 3). Although

individual changes from baseline were observed, no clinically important trends were evident. Some out-of-range clinical laboratory values were reported for clinical haematology and clinical chemistry parameters. There was no apparent relationship to dose of OMS906 and none of the abnormalities were reported as TEAEs or considered clinically significant.

Adverse Events

See *Table 2* for a summary of TEAEs.

Table 3: Summary of Treatment-emergent Adverse Events by System Organ Class (Safety Analysis Set)

System Organ Class	OMS906 8 mg/kg N=6 n (%) [E]	OMS906 12 mg/kg N=6 n (%) [E]	Pooled Placebo N=4 n (%) [E]	Overall N=16 n (%) [E]
Infections and infestations	3 (50.0) [3]	1 (16.7) [2]	2 (50.0) [4]	6 (37.5) [9]
Reproductive system and breast disorders	1 (16.7) [2]	0	1 (25.0) [1]	2 (12.5) [3]
Gastrointestinal disorders	1 (16.7) [1]	0	1 (25.0) [1]	2 (12.5) [2]
Nervous system disorders	1 (16.7) [1]	0	1 (25.0) [1]	2 (12.5) [2]
Skin and subcutaneous tissue disorders	1 (16.7) [1]	0	1 (25.0) [1]	2 (12.5) [2]
Musculoskeletal and connective tissue disorders	0	1 (16.7) [2]	0	1 (6.3) [2]
Immune system disorders	1 (16.7) [1]	0	0	1 (6.3) [2]

Abbreviations: E = number of events; N = number of subjects who received at least one dose of OMS906 at the stated dose or placebo; n = number of subjects with events.

% = n/N*100.

Treatment-emergent adverse event was defined as any adverse event that began or worsened after administration of the study medication.