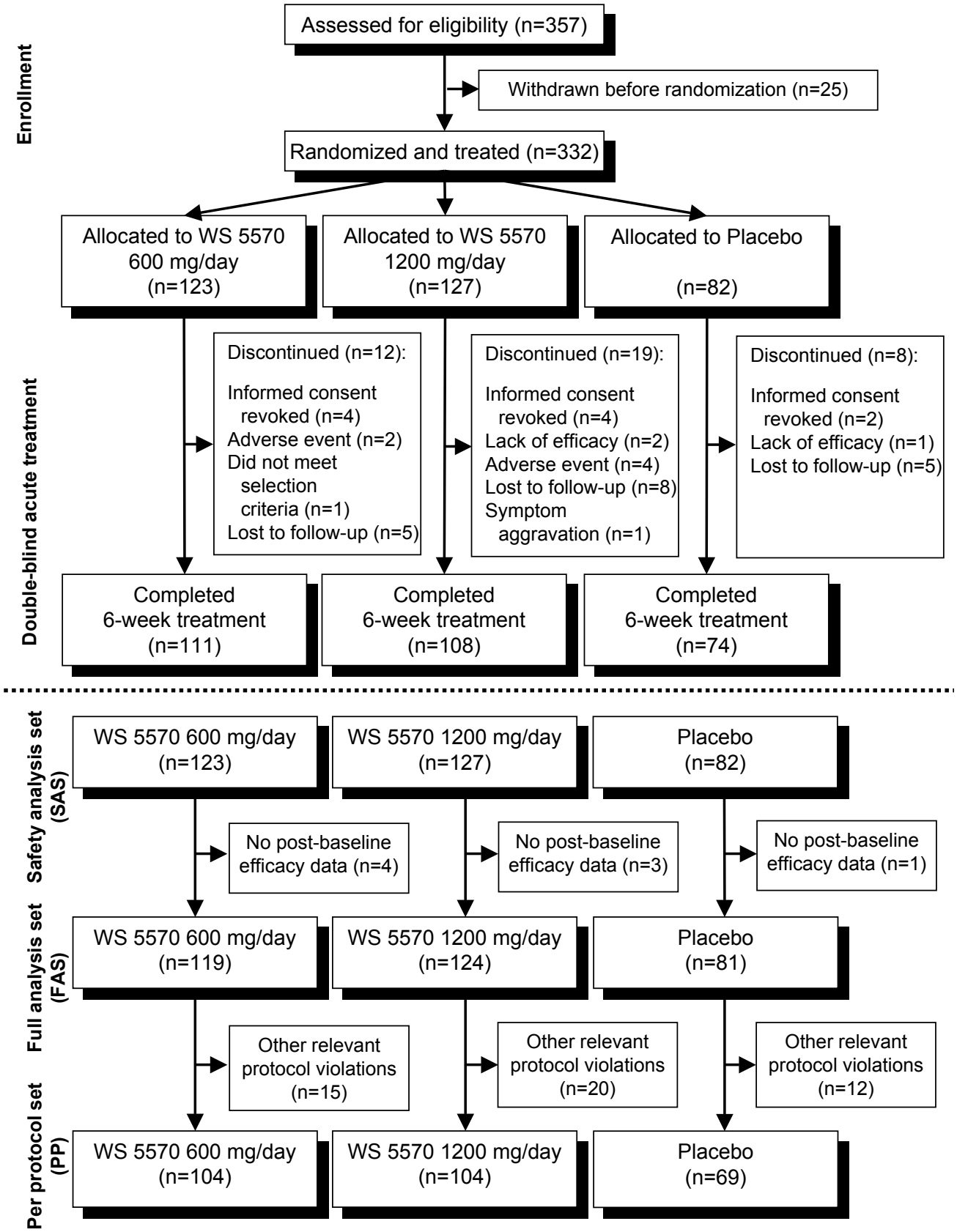
Enrollment
Assessed for eligibility (n=357)
Withdrawn before randomization (n=25)
Randomized and treated (n=332)
Allocated to WS 5570 600 mg/day (n=123)
Allocated to WS 5570 1200 mg/day (n=127)
Allocated to Placebo (n=82)
Double-blind acute treatment
Discontinued (n=12):
Informed consent revoked (n=4)
Adverse event (n=2)
Did not meet selection criteria (n=1)
Lost to follow-up (n=5)
Discontinued (n=19):
Informed consent revoked (n=4)
Lack of efficacy (n=2)
Adverse event (n=4)
Lost to follow-up (n=8)
Symptom aggravation (n=1)
Discontinued (n=8):
Informed consent revoked (n=2)
Lack of efficacy (n=1)
Lost to follow-up (n=5)
Completed 6-week treatment (n=111)
Completed 6-week treatment (n=108)
Completed 6-week treatment (n=74)
Safety analysis set (SAS)
WS 5570 600 mg/day (n=123)
WS 5570 1200 mg/day (n=127)
Placebo (n=82)
No post-baseline efficacy data (n=4)
No post-baseline efficacy data (n=3)
No post-baseline efficacy data (n=1)
Full analysis set (FAS)
WS 5570 600 mg/day (n=119)
WS 5570 1200 mg/day (n=124)
Placebo (n=81)
Other relevant protocol violations (n=15)
Other relevant protocol violations (n=20)
Other relevant protocol violations (n=12)
Per protocol set (PP)
WS 5570 600 mg/day (n=104)
WS 5570 1200 mg/day (n=104)
Placebo (n=69)