Assessed for eligibility (n=357)

Withdrawn before randomization (n=25)

Randomized and treated (n=332)

Allocated to WS 5570
600 mg/day (n=123)

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)

Completed 6-week treatment (n=111)

Allocated to WS 5570
1200 mg/day (n=127)

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)

Completed 6-week treatment (n=108)

Allocated to Placebo (n=82)

Discontinued (n=8):
- Informed consent revoked (n=2)
- Lack of efficacy (n=1)
- Lost to follow-up (n=5)

Completed 6-week treatment (n=74)

Double-blind acute treatment enrollment

Allocated to WS 5570 600 mg/day (n=123)

Discontinued (n=19):
- Informed consent revoked (n=4)
- Adverse event (n=2)
- Lack of efficacy (n=2)
- Lost to follow-up (n=8)
- Symptom aggravation (n=1)

Completed 6-week treatment (n=119)

Allocated to WS 5570 1200 mg/day (n=127)

Discontinued (n=8):
- Informed consent revoked (n=2)
- Lack of efficacy (n=1)
- Lost to follow-up (n=5)

Completed 6-week treatment (n=124)

Allocated to Placebo (n=81)

Discontinued (n=8):
- Informed consent revoked (n=2)
- Lack of efficacy (n=1)
- Lost to follow-up (n=5)

Completed 6-week treatment (n=69)

No post-baseline efficacy data (n=4)

Other relevant protocol violations (n=15)

Safety analysis set (SAS)

Full analysis set (FAS)

Per protocol set (PP)