

Assessed for eligibility (n = 35)

Excluded (n = 1)

Failed eligibility criteria (n = 1)

Randomised (n = 34)

Cohort A

(masitinib plus cholinesterase
inhibitor and/or memantine)

Cohort B

(placebo plus cholinesterase
inhibitor and/or memantine)

Allocated to masitinib-arm (n = 26)

Received allocated intervention (n = 26)

Start dose of 3 mg/kg/day (n = 12)

Start dose of 6 mg/kg/day (n = 14)

Allocated to placebo-arm (n = 8)

Received allocated intervention (n = 8)

Premature discontinuation (n = 17)

Adverse event (n = 9)

Protocol violation (n = 1)

Withdrawal of consent (n = 2)

Investigator death (n = 7)

Premature discontinuation (n = 2)

Adverse event (n = 0)

Protocol violation (n = 1)

Withdrawal of consent (n = 0)

Investigator death (n = 1)

On-going at week 24 (n = 9)

Primary endpoint analysis* (n = 16)

On-going at week 24 (n = 6)

Primary endpoint analysis* (n = 6)

*Week 12 data for closed study centre
imputed using LOCF for week 24.