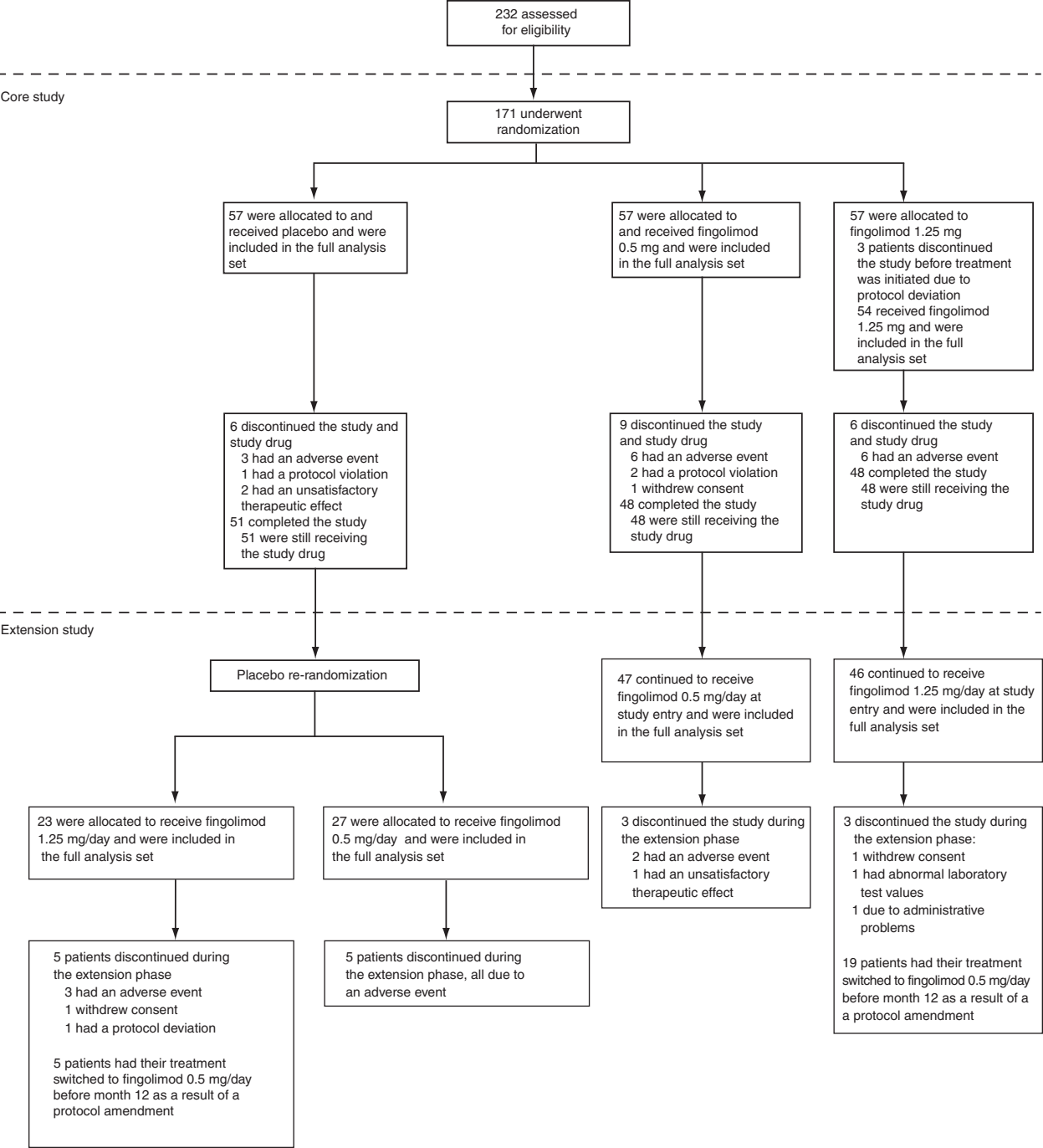
232 assessed for eligibility
Core study
171 underwent randomization
57 were allocated to and received placebo and were included in the full analysis set
57 were allocated to and received fingolimod 0.5 mg and were included in the full analysis set
57 were allocated to fingolimod 1.25 mg
3 patients discontinued the study before treatment was initiated due to protocol deviation
54 received fingolimod 1.25 mg and were included in the full analysis set
6 discontinued the study and study drug
3 had an adverse event
1 had a protocol violation
2 had an unsatisfactory therapeutic effect
51 completed the study
51 were still receiving the study drug
9 discontinued the study and study drug
6 had an adverse event
2 had a protocol violation
1 withdrew consent
48 completed the study
48 were still receiving the study drug
6 discontinued the study and study drug
6 had an adverse event
48 completed the study
48 were still receiving the study drug
Extension study
Placebo re-randomization
47 continued to receive fingolimod 0.5 mg/day at study entry and were included in the full analysis set
46 continued to receive fingolimod 1.25 mg/day at study entry and were included in the full analysis set
23 were allocated to receive fingolimod 1.25 mg/day and were included in the full analysis set
27 were allocated to receive fingolimod 0.5 mg/day and were included in the full analysis set
3 discontinued the study during the extension phase
2 had an adverse event
1 had an unsatisfactory therapeutic effect
3 discontinued the study during the extension phase:
1 withdrew consent
1 had abnormal laboratory test values
1 due to administrative problems
19 patients had their treatment switched to fingolimod 0.5 mg/day before month 12 as a result of a a protocol amendment
5 patients discontinued during the extension phase
3 had an adverse event
1 withdrew consent
1 had a protocol deviation
5 patients had their treatment switched to fingolimod 0.5 mg/day before month 12 as a result of a protocol amendment
5 patients discontinued during the extension phase, all due to an adverse event