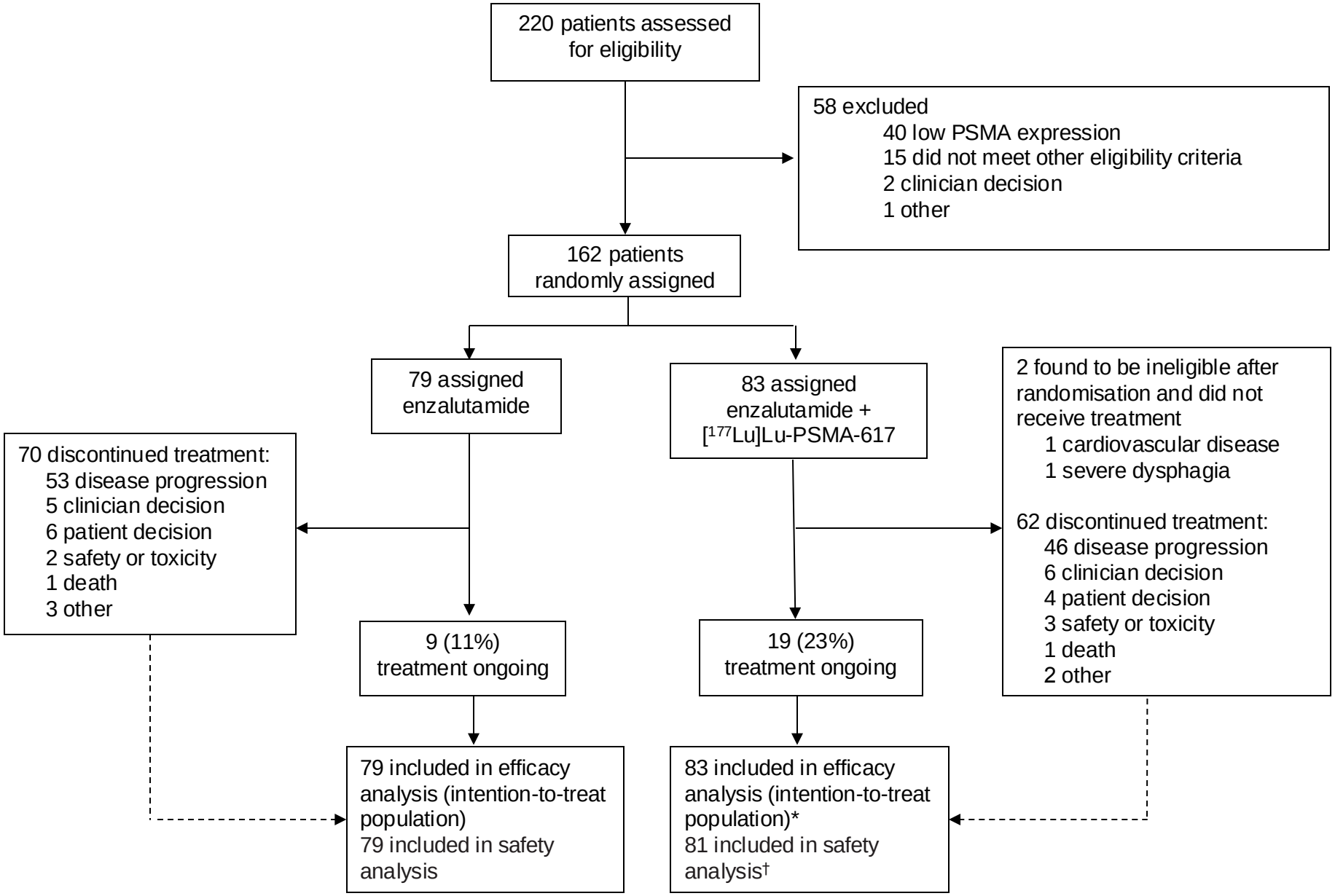
220 patients assessed for eligibility
58 excluded
40 low PSMA expression
15 did not meet other eligibility criteria
2 clinician decision
1 other
162 patients randomly assigned
79 assigned enzalutamide
83 assigned enzalutamide + [177Lu]Lu-PSMA-617
2 found to be ineligible after randomisation and did not receive treatment
1 cardiovascular disease
1 severe dysphagia
62 discontinued treatment:
46 disease progression
6 clinician decision
4 patient decision
3 safety or toxicity
1 death
2 other
70 discontinued treatment:
53 disease progression
5 clinician decision
6 patient decision
2 safety or toxicity
1 death
3 other
9 (11%) treatment ongoing
19 (23%) treatment ongoing
79 included in efficacy analysis (intention-to-treat population)
79 included in safety analysis
83 included in efficacy analysis (intention-to-treat population)*
81 included in safety analysis†