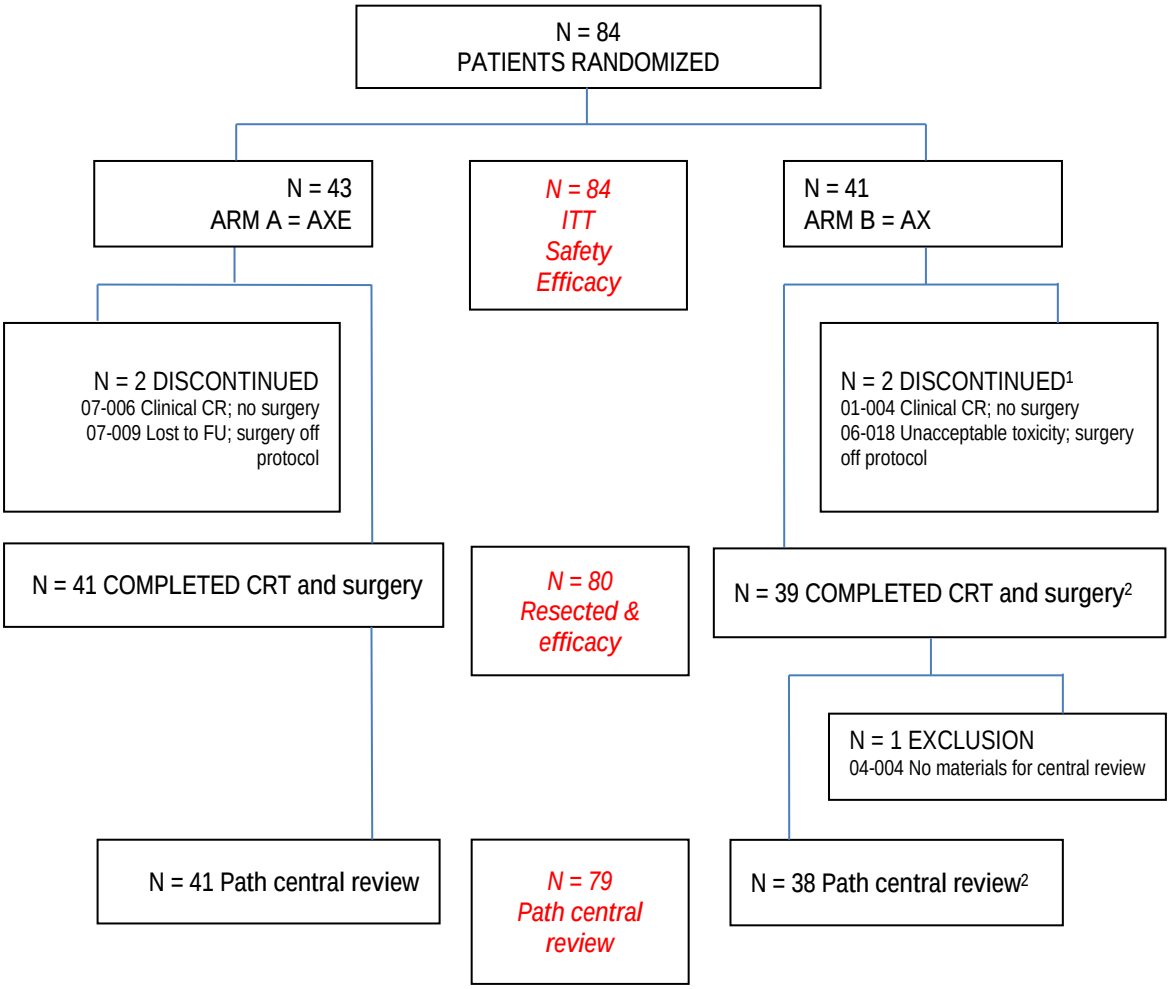
Figure 4. Patient disposition ITT and efficacy sets (CONSORT)



Notes:
Abbreviations: CRT= chemoradiotherapy; CR=complete response; Path=Pathologic
[1] Patient 06-013 (Arm B) deceased 3 days after surgery is also considered discontinued (during 30 day mandatory postoperative follow-up). However, this patient can be included in all efficacy sets as surgery was performed per protocol and materials for central review were available.
[2] Patient 04-011 (Arm B) completed CRT and surgery as per protocol. Materials were available for central review (included in efficacy sets above). However this patient was only borderline eligible in terms of tumour position and MRI tumour characteristics [CRM at 4 mm; distance of tumour to anal verge > 5cm (6 based on colonoscopy report); see inclusion criteria] which were considered to determine a slightly better prognostic compared to the other patients in group. The efficacy analysis was performed with and without this patient.

A listing of all patients discontinued from the study with reasons is provided in Appendix 16.2.1.

All 84 patients started treatment per protocol, were considered eligible for and entered the safety analysis. The intent to treat patient set was the same with the safety and the per protocol sets for this analysis.

Efficacy: one patient (04-011) was borderline eligible in terms of tumour position and MRI tumour characteristics [CRM at 4 mm; distance of tumour to anal verge > 5 cm (6 based on colonoscopy report); see inclusion criteria] which were considered to determine