Supplementary

Table S1 Ongoing clinical trials which investigate organ preservation in the context of a total neoadjuvant paradigm

Trial	Country	Design (anticipated enrollment)	Eligibility	Treatment schedule	Primary outcome measure
ACO/ARO/AIO-18.1 (NCT04246684)	Germany	Phase III RCT (N=702)	pMMR; cT3-4, N0 or cT1-4, N+; <12 cm anal verge	Arm 1: induction SCRT followed by consolidation FOLFOX ×9 or CAPOX ×6 Arm 2: induction LCCRT followed by consolidation FOLFOX ×6 or CAPOX ×4	3-year organ preservation
CCHOWW (NCT05000697)	Brazil	Phase II RCT (N=200)	pMMR; cT2-3, N0 or cT1-4, N+; <8 cm anal verge	Arm 1: induction LCCRT followed by consolidation FOLFOX ×4 or CAPOX ×4 Arm 2: induction LCCRT followed by consolidation capecitabine ×4	Clinical complete response rate achieved within 18 weeks from completion of radiation
ENSEMBLE (NCT0564651136)	Japan	Phase III RCT (N=608)	pMMR; cT3-4, N0 or cT1-4, N+; <12 cm anal verge	Arm 1: induction SCRT followed by consolidation CAPOX ×6 Arm 2: induction SCRT followed by consolidation CAPOXIRI ×6	3-year organ preservation-adapted disease-free survival
JANUS (NCT05610163)	USA	Phase II/III RCT (N=312/760)	pMMR; cT4, N0 or cT1-4, N+; ≤12 cm anal verge	Arm 1: induction LCCRT followed by consolidation FOLFOX ×8 or CAPOX ×5 Arm 2: induction LCCRT followed by consolidation FOLFIRINOX ×8	Phase II: clinical complete response rate Phase III: 3-year disease-free survival

RCT, randomized control trial; N, number; pMMR, mismatch repair proficient; N0, lymph node negative; N+, lymph node positive; SCRT, short-course radiotherapy; FOLFOX, fluorouracil, leucovorin, oxaliplatin; CAPOX, capecitabine, oxaliplatin; LCCRT, long-course chemoradiotherapy; CAPOXIRI, capecitabine, oxaliplatin, and irinotecan; FOLFIRINOX, fluorouracil, leucovorin, oxaliplatin, and irinotecan.

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