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## Organ preservation in rectal cancer: the randomised STAR-TREC phase II trial

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### Purpose or Objective

No randomised trials have compared non-operative organ preservation (OP) therapy for early-stage rectal cancer versus standard of care (SoC) using total mesorectal excision (TME) alone. STAR-TREC evaluated the feasibility of recruiting to a study comparing SoC versus two contrasting OP strategies, optimised for treatment of early tumours.

### Materials and Methods

STAR-TREC was a prospective, randomised, open-label, feasibility study in the UK, Netherlands and Denmark. Patients with biopsy proven adenocarcinoma of the rectum, staged  $\leq$ mrT3b N0 M0,  $\leq$ 40mm diameter, ECOG 0-1 were randomised in a 1:1:1 ratio to TME, OP via mesorectal short-course radiotherapy (5x5 Gy), or OP via mesorectal chemoradiotherapy (25x2 Gy + capecitabine). Standardised response assessment classified OP cases as complete response for no further treatment, partial response for transanal endoscopic microsurgery or poor response for TME by 20 weeks. Surveillance following OP consisted of 3-monthly endoscopy/MRI. All cases had CT thorax/abdomen/pelvis at 24 months (m). The primary outcome was recruitment rate over 2 years, with randomisation of 120 international cases calculated as sufficient to support a phase III trial. Secondary outcomes included acute toxicity, stoma and OP rates at 12m, disease free survival (DFS) and non-regrowth DFS (NRDFS) at 24m. For the purposes of the phase II analysis (as the phase III trial is still ongoing and to maintain blinding of outcomes) we group patients who underwent organ preservation giving a pseudo ratio of 1:2 in favour of organ preservation.

### Results

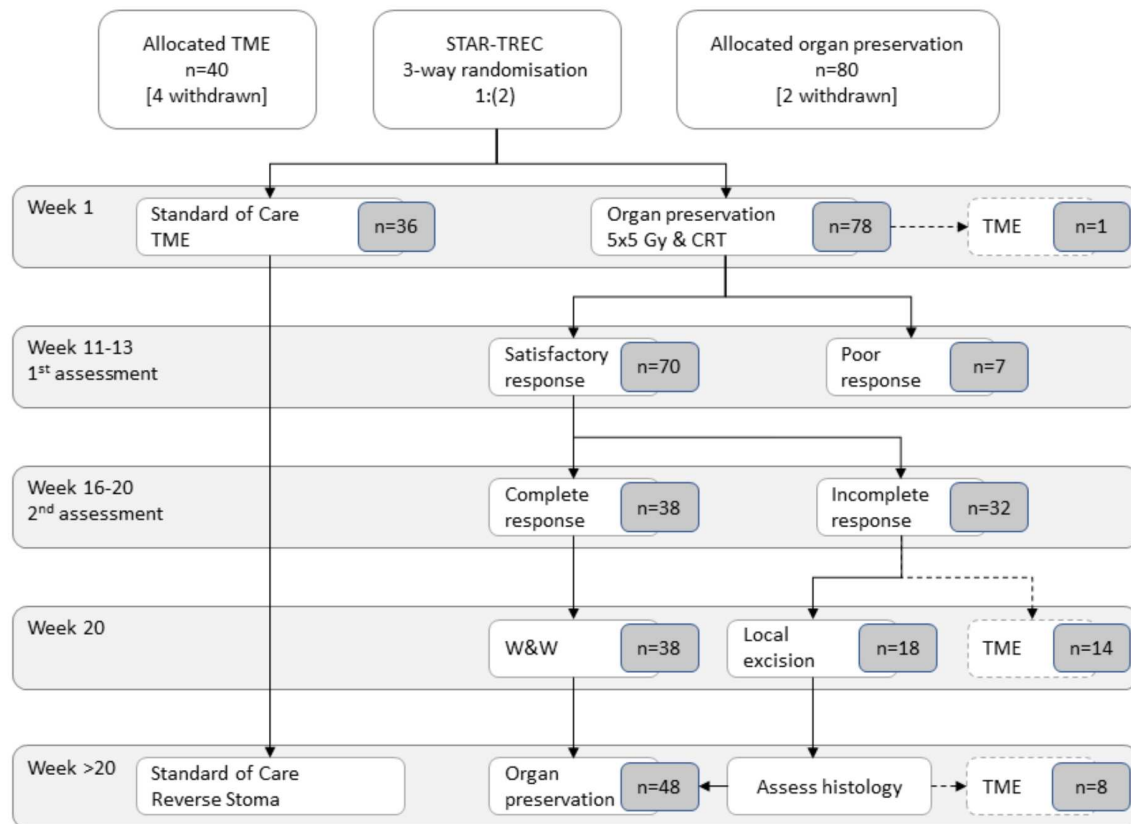
Recruitment endpoints of 120 patients were met on 28 Oct 2019. Distribution of baseline characteristics was not significantly different between the SoC and OP group, with 75% and 74% males and a median age of 67.3 and 65.2 years respectively. Patients had a Tx/T1/T2/T3a tumor in 97.5% and 95% of the SoC and OP group respectively. Response rates for the OP group are presented in Figure 1. Key secondary outcomes are tabulated by intention to treat in Figure 2. No 6-month mortality occurred. NRDFS at 2 years was similar between the two groups.

### Conclusion

OP pathways optimised for early tumours reduce acute surgical morbidity without introducing substantial radiation toxicity to achieve OP in 60% with no increase in NRDFS at 24m compared to SoC. STAR-TREC phase

III will determine the optimal strategy for achieving OP (STAR-TREC Phase III protocol. Colorectal Disease 2022).

Figure 1.



Tabel 1.

		Standard of Care N=40	Organ Preservation N=80
Acute toxicity ≤ 4 weeks	Radiation ≥G3	-	3 (3.8%)
	Major surgical	7 (17.5%)	9 (11.2%)
Stoma at 12 months		11 (27.5%)	14 (17.5%)
OP at 12 months		-	48 (60.0%)
2-yr Non regrowth DFS		97.2%	98.6%
2-yr DFS		88.8%	74.2%