EMERALD PANCREAS

ESTRO 2025

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Clinical outcomes from EMERALD trial: A phase I evaluating ultra-hypofractionated MR-Guided Adaptive SABR (SMART) for localized pancreatic cancer (ISRCTN10557832)

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GenesisCare Experts in cancer care

Oxford University Hospitals NHS Foundation Trust

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Conflict of interest:

None

Funding

- Oxford University - GenesisCare Collaboration Fund
- John Black Charitable Foundation
- Oxford Institute for Radiation Oncology, University of Oxford

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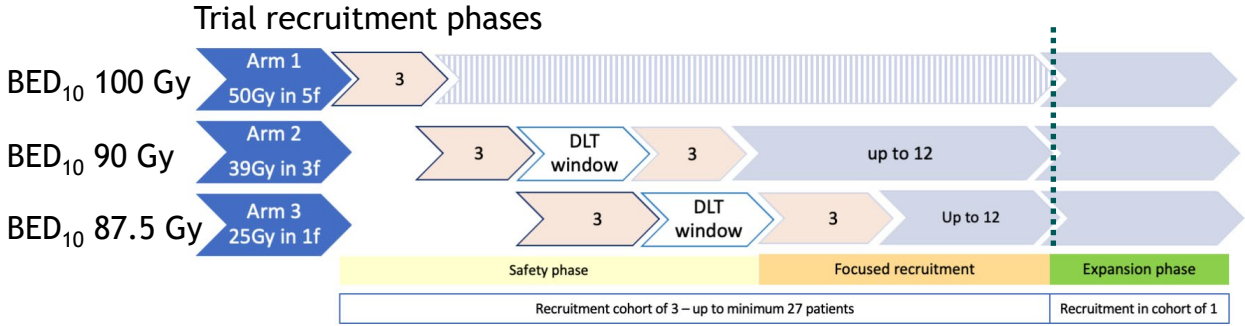
Published protocol
Teoh S, et al.
BMJ Open 2023;13:e068906

Methods

- Single centre, phase I, non-randomized safety study.
- MRIdian® *(0.35 T MR-Linac, ViewRay Systems)*
- Inclusion: Localised or locally recurrent PDAC patients were eligible



Dose Limiting Toxicity
(DLT period: 3 months)

- G3 upper GI Bleed
- Uncontrolled G4 nausea/vomiting
- Any Grade GI fistula
- G4 acute pancreatitis
- Non-tumor vascular events

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Results

- **August/2022-October/2023 25 patients enrolled, 20 underwent SMART**
- Arm1 (5fx) n = 4, Arm2 (3fx) n = 8, Arm 3 (1fx) n = 8
- Demographics: Median age 71 years (range 58-85), majority in head of pancreas (60%,n=12) and 95% (n=19) received induction chemotherapy

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NO DLT WERE SEEN

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Table 1. Toxicity according CTCAE

	Arm 1 (5fx)	Arm 2 (3fx)	Arm 3 (1fx)	Total
Patients, n	4	8	8	20
Patients with SMART-related AEs (any grade), n (%)	3 (75)	6 (75)	8 (100)	17 (85)
Patients with G3 SMART-related AEs, n (%)	2 (50)	2 (25)	2 (25)	6 (30)
Fatigue	0 (0)	1 (12.5)	2 (25)	3 (15)
Biliary Obstruction/sepsis	2 (50)	0 (0)	0 (0)	2 (10)
Duodenal Obstruction	0 (0)	1 (12.5)	0 (0)	1 (5)

CTCAE=Common Terminology Criteria for Adverse Events; N= number of patients; AEs= Adverse Events; GI= gastrointestinal; G= grade.

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- Demographics: Median age 71 years (range 58-85), majority in head of pancreas (60%,n=12) and 95% (n=19) received induction chemotherapy

One incidence of fatal (G5) GI bleeding outside the DLT period
(relationship to SMART could not be excluded)

- 7 months from SMART
- Local PD (portal-vein involved)
- Anti-coagulation

*Median follow-up from SMART: 9.8 months (range 3.5-20.3 months)

Table 2. Clinical Outcomes				
	Arm 1 (5F)	Arm 2 (3F)	Arm 3 (1F)	Total
Patients, n (%)	4	8	8	20
Survival Outcomes from SMART, rate % (CI 95%)				
12-month OS	37.5 (8.4 - 100.0)	85.7 (63.3 - 100.0)	52.5 (24.5 - 100.0)	62.9 (42.7 - 92.5)
18-month OS	37.5 (8.4 - 100.0)	85.7 (63.3 - 100.0)	26.3 (5.4 - 100.0)	50.3 (28.8 - 90.2)
12-month LPFS	50.0 (18.8 - 100.0)	72.9 (46.8 - 100.0)	56.2 (28.1 - 100.0)	62.3 (43.4 - 89.5)
18-month LPFS	50.0(18.8 - 100.0)	72.9 (46.8 - 100.0)	28.1 (5.8 - 100.0)	49.8 (28.2 - 88.0)
Survival Outcomes from Diagnosis, rate % (CI 95%) *				
12-month OS	75.0 (42.6 - 100.0)	100 (100.0 - 100.0)	100 (100.0 - 100.0)	94.1 (83.6 - 100.0)
24-month OS	37.5 (8.4 - 100.0)	83.3 (58.3 - 100.0)	50.0 (22.5 - 100.0)	56.6 (35.0 - 91.6)
12-month LPFS	50.0 (18.8 - 100)	100.0 (100-100.0)	85.7 (63.3 - 100.0)	82.4 (66.1 - 100.0)
24-month LPFS	50.0 (18.8 - 100)	66.7 (37.9 - 100)	51.4 (23.6 - 100.0)	53.3 (32.6 - 87.2)

*Dosimetric and treatment parameters are presented on poster number **E25-3471***

Conclusion

Ultra-hypofractionated SMART for localised pancreatic cancer can be delivered in single-fraction and three fractions with acceptable toxicity and clinical outcomes.

These regimes merit further investigation in phase II/III trials to evaluate clinical benefit and cost-effectiveness