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Comparison of resected *vs*. non-resected patients with unresectable locally advanced pancreatic cancer (LAPC) receiving P-32 microparticles with gemcitabine/nab-paclitaxel or FOLFIRINOX chemotherapy in the PanCO study

Paul J Ross

Guy's & St Thomas' Hospital NHS Foundation Trust, London, UK
on behalf of the PanCO investigators

Disclosures

- Consulting/Advisory fees from – Amgen, AstraZaneca, Eisai, Roche, Servier, Sirtex
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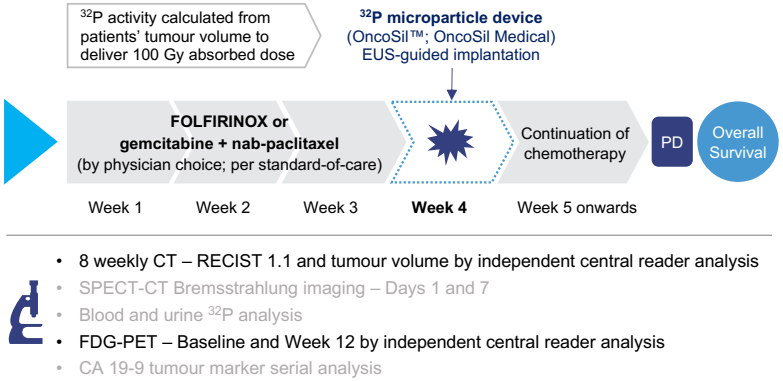
PanCO Study

Design and Objective
(ClinicalTrial.gov Identifier NCT03003078)

Key Eligibility Criteria
- Histologically or cytologically proven pancreatic adenocarcinoma
- Unresectable LAPC
- Target tumour diameter 2−6 cm
- ECOG Performance Status 0 to 1
- No distant metastases
- No prior radiotherapy or chemotherapy for pancreatic cancer



Primary Objective: To assess the **safety** of the ^{32}P microparticle device and determine the **feasibility of the administration** approach in the setting of unresectable locally advanced pancreatic cancer (LAPC)

- The PanCO study reported:
  - No serious device or radiation-related toxicities
  - Local disease control rate at 16 weeks: 82%
  - ITT ORR: 29.8%; DCR: 95.7%
  - Resection rate of 23.8%
  - PFS median 9.3 months,1-year rate 32.8%
  - OS median 15.5 months, 1-year rate 63.4%

We present a *post-hoc* analysis of the resected *vs*. non-resected cohorts in the PanCO study

Ross PJ et al. *ESMO Open* February 2022; **7** (1): 100356.

Abbreviations: EUS, endoscopic ultrasound; ITT, intention-to-treat population; PP, per protocol population.

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^{32}P activity calculated from patients' tumour volume to deliver 100 Gy absorbed dose

^{32}P microparticle device (OncoSil™; OncoSil Medical) EUS-guided implantation

FOLFIRINOX or gemcitabine + nab-paclitaxel (by physician choice; per standard-of-care) → Continuation of chemotherapy → PD → Overall Survival

Week 1 | Week 2 | Week 3 | **Week 4** | Week 5 onwards

- 8 weekly CT – RECIST 1.1 and tumour volume by independent central reader analysis
- SPECT-CT Bremsstrahlung imaging – Days 1 and 7
- Blood and urine ^{32}P analysis
- FDG-PET – Baseline and Week 12 by independent central reader analysis
- CA 19-9 tumour marker serial analysis

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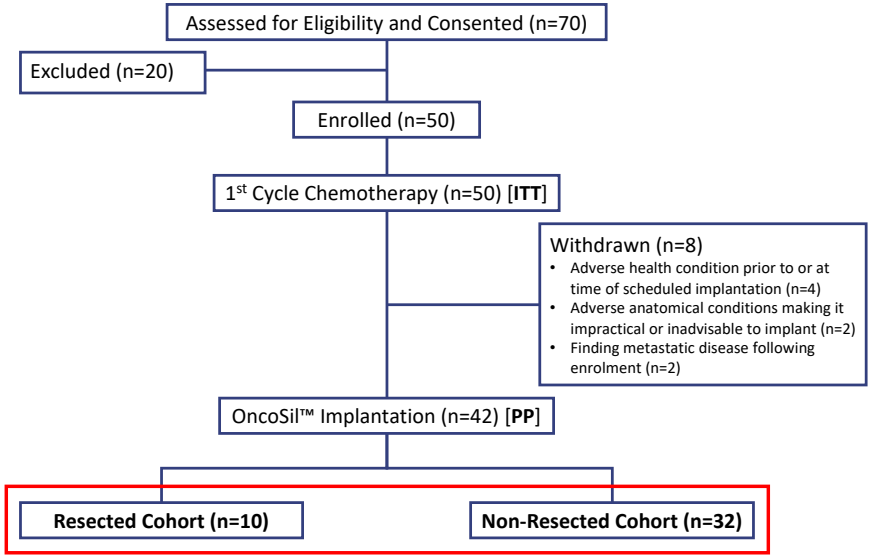
Participant Flow



Recruitment period: March 2017 to June 2018

Patients	Australia (5 sites)	Belgium (1 site)	UK (4 sites)	Total (10 sites)
Enrolled **[ITT]**	36	2	12	50
Implanted **[PP]**	31	2	9	42

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Baseline Characteristics of the Resected *vs*. Non-Resected Cohorts (PP)

Characteristic, n (%) unless stated		PP Population (N = 42)	Resected Patients (n = 10)	Non-Resected Patients (n = 32)
Age, years	Median (Range)	66 (49–84)	65 (56–78)	68 (49–84)
Sex	Male : Female	27 (64.3%) : 15 (35.7%)	4 (40%) : 6 (60%)	23 (71.9%) : 9 (28.1%)
Race	White/Caucasian Black/African American Asian	34 (80.1%) 3 (7.1%) 5 (11.9%)	8 (80%) 0 2 (20%)	26 (81.3%) 3 (9.4%) 3 (9.4%)
ECOG Performance Status	0 : 1	24 (57.1%) : 18 (42.9%)	8 (80%) : 2 (20%)	16 (50.0%) : 16 (50.0%)
CA 19-9, (U/mL) in participants with baseline >35 U/mL [n=33]	Median (Range) Mean	292 (38–6576) 850	191.5 (1–1479) 397.5	290.5 (38–6576) 941
Pancreatic tumour location	Head : Body	34 (81.0%) : 8 (19.0%)	9 (90%) : 1 (10%)	25 (78.1%) : 7 (21.9%)
Target lesion longest diameter*, cm	Median (Range)	4.5 (3.0–7.1)	4.5 (3.0–6.6)	4.5 (3.0–7.1)
Tumour volume*, cc	Median (Range)	24.4 (7.9–68.7)	23.2 (9.9–50)	24.4 (7.9–68.7)
Study Days to OncoSil Implant, days	[n=42] Median (Range)	31 (21–77)	39 (26–76)	31 (21–77)
Chemotherapy	gemcitabine + nab-paclitaxel FOLFIRINOX	34 (80.1%) 8 (19.9%)	9 (90%) 1 (10%)	25 (78.1%) 7 (21.9%)

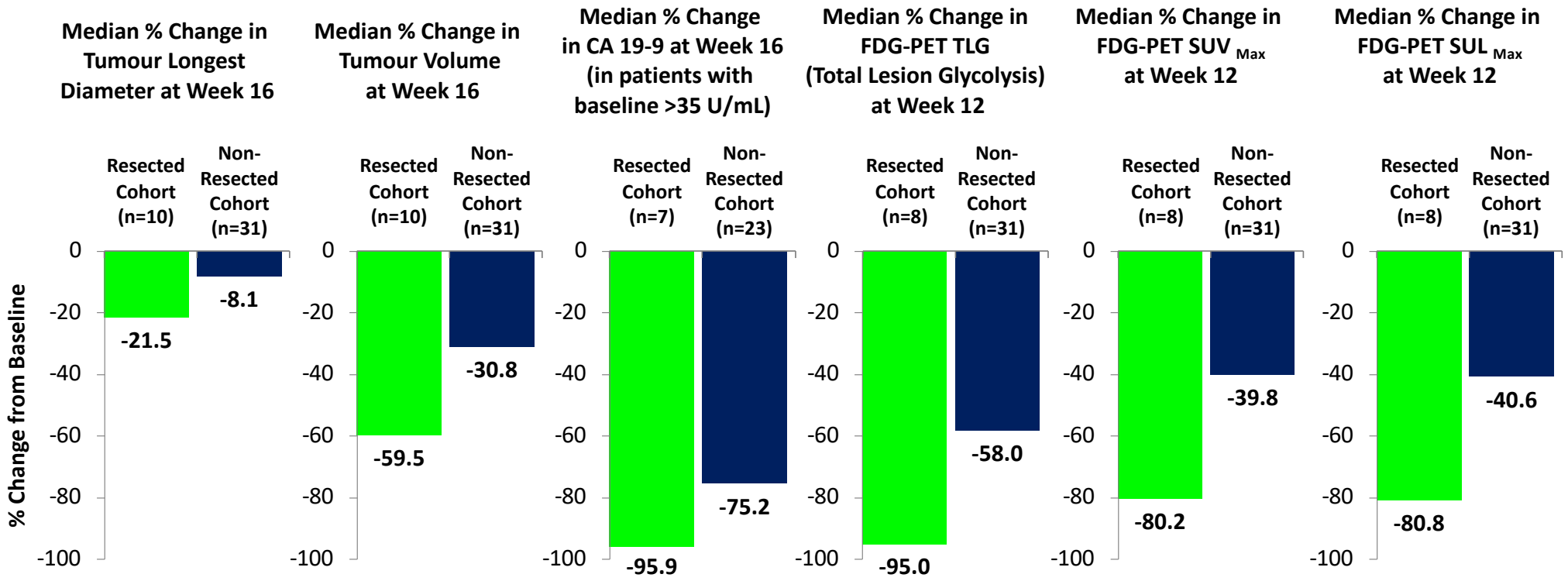
Surgical Resection

Surgical Resection with Curative Intent	Resected Patients (n = 10)	Non-Resected Patients (n = 32)
R0 Margin Status *vs.* R1, n (% of resections)	8 (**80.0%**) *vs.* 2 (20.0%)	na
RDI for gemcitabine/nab-paclitaxel at 4 cycles (n)	70.6% (n=9)	54.2% (n=25)
RDI for FOLFIRINOX at 6 cycles (n)	82.9% (n=1)	71.2% (n=7)

- 10 participants underwent pancreaticoduodenectomy (23.8% of PP population), 80% with R0 margins
  - 9 resected patients received gemcitabine + nab-paclitaxel; 1 received FOLFIRINOX
- HPB surgeons noted reduction in the fibrosis of the tumours along blood vessels and favourable tissue planes
- At least 4 additional participants were sufficiently downstaged to be technically considered for surgical resection, but could not undergo surgery due to metastases, concomitant co-morbidities or other considerations: 33% of participants receiving P-32 microparticles were technically considered resectable or were resected with curative intent

Abbreviations: RDI, Relative Dose Intensity

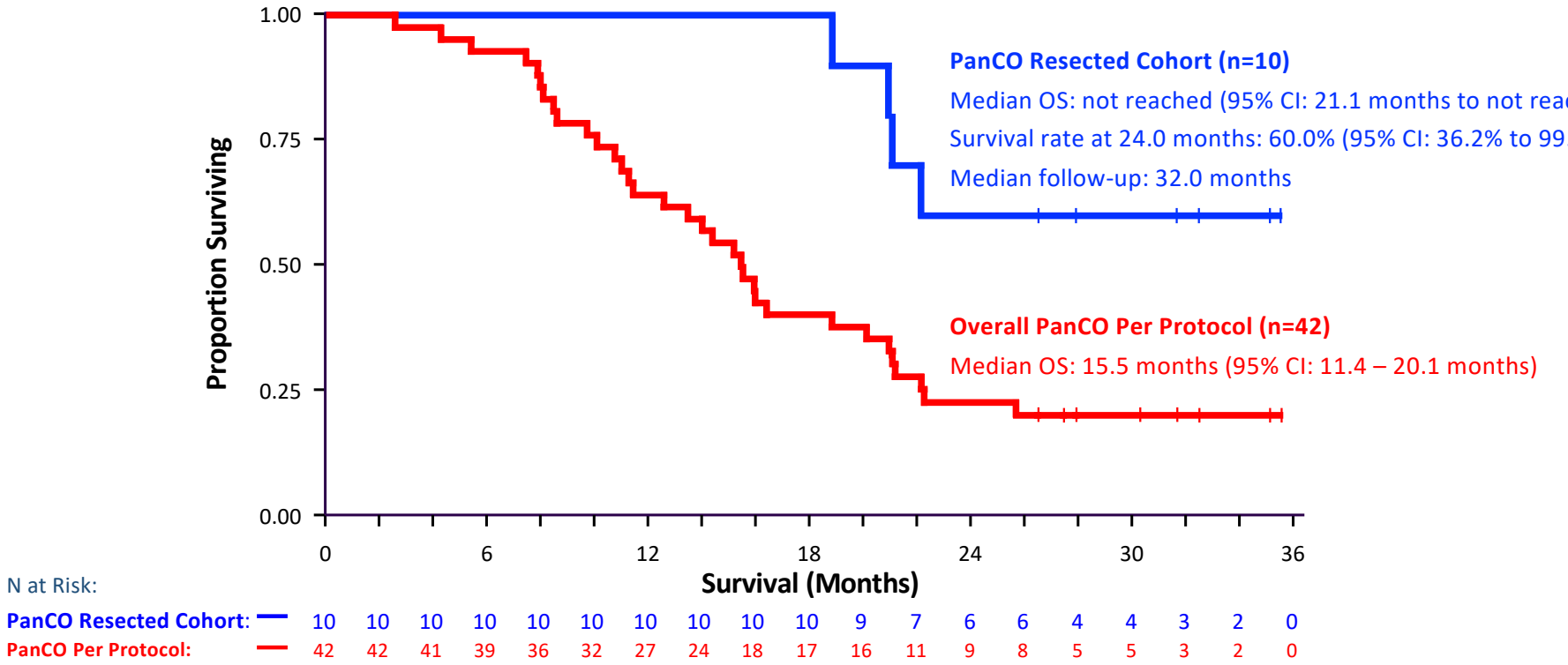
Resected *vs.* Non-Resected PP Cohort: Tumour Response at Week 16 or 12



All assessments exclude post-resection imaging. Tumour longest diameters and volumes calculated by independent central reader at each imaging assessment; volumes calculated using Voxels of Interest and eMass software (ERT; Brussels). Implanted participants with evaluable PET scan assessments at Baseline and at Week 12.

Resected Patients: Kaplan-Meier Analysis of Overall Survival

- At a median follow-up of 32.0 months, 6 resected patients remained alive at study completion (range 26.4–35.3 months) and 5 were disease-free; 4 patients died at 18.8–22.1 months from enrolment (11.3–17.9 months from resection)



Conclusions: Resected *vs*. non-resected cohorts

- EUS-guided P-32 microparticle implantation appears safe, with encouraging clinical outcomes and may convert unresectable LAPC to surgical resection
- Nearly one-in-four PP participants (23.8%) underwent surgical resection with curative intent and one-in-three (33.3%) were technically resectable
- Baseline characteristics of study participants who underwent surgical resection were similar to those who were not resected
- Complications in the 30 days' post-resection were in line with surgical experience
- Resected participants had a substantial response to treatment compared to non-resected participants, particularly decrease in tumour volume, and encouraging survival
- Further clinical studies adding P-32 microparticles to SoC chemotherapy are planned

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