PREOPANC-4 RCT

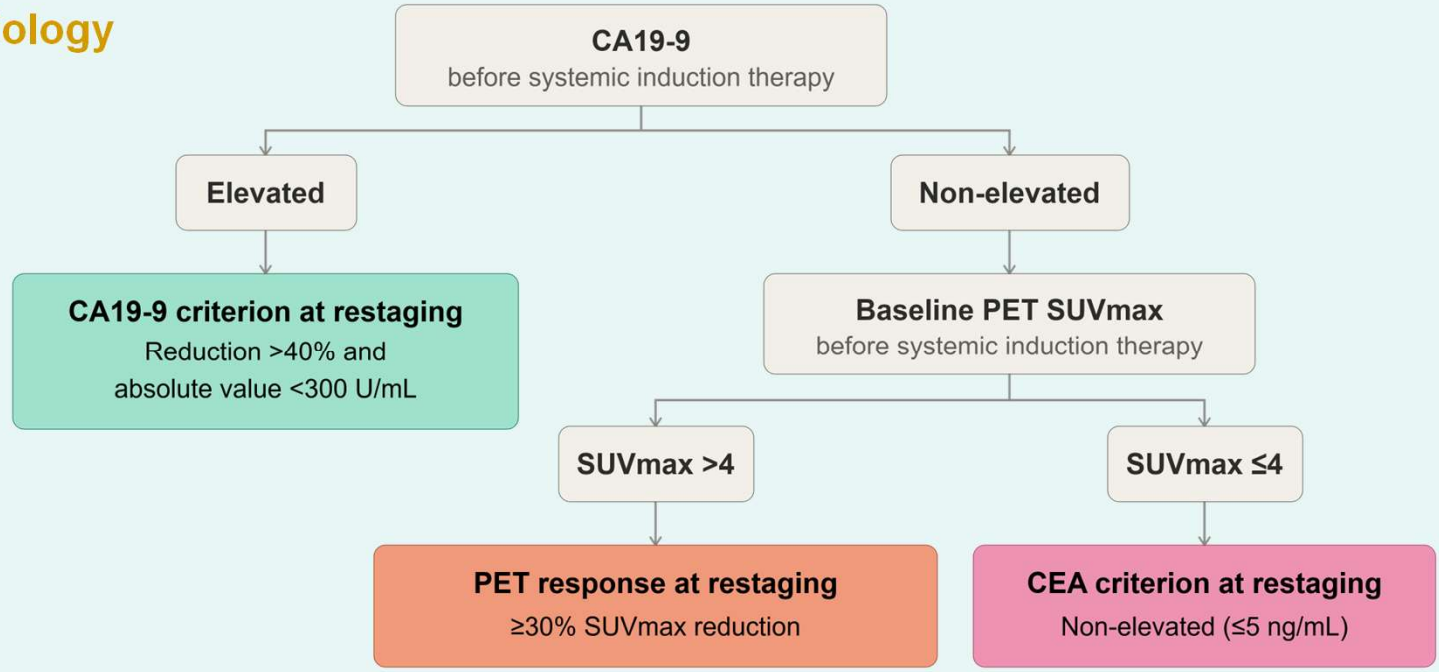
Inclusion criteria

Screen for eligibility after ≥ 3 months of induction systemic therapy

Anatomy

- **≥ 18 yrs** with pathology-proven **NCCN LAPC** version 2025 (see protocol);
- RECIST non-progressive disease;
- **No downstaging** to (borderline) resectable tumour;
- Surgical resection and radiation feasible according to local MDT.

Biology



NB. If serum **CA19-9** after systemic therapy is **>150** U/mL, **negative staging laparoscopy** before randomization is required, unless already performed.

Condition

- **ECOG** / WHO performance status **0-1** + **fit** for surgery & systemic therapy.

Exclusion criteria

- **Prior induction radiotherapy** for pancreatic cancer or another periampullary carcinoma; radiotherapy is allowed only as a single 8 Gy fraction in case of tumour bleeding.
- **Clinical deterioration** during induction systemic therapy or increased suspected tumour-related pain that is not explained by other potential causes of pain (e.g. pancreatitis or stent dysfunction).
- **History of malignancy**, except under the following conditions: no evidence of disease, diagnosis was >3 years before pancreatic cancer diagnosis, and life expectancy is >5 years from date of inclusion.
- **Tumours directly invading gastrointestinal hollow organs**, except the duodenum.

If you want to discuss your patient in the upcoming online LAPC Expert Panel, please contact preopanc4rct@amsterdamumc.nl

PREOPANC-4 RCT

PALACROS

DPCG
Dutch Pancreatic Cancer Group

1. Eligible patients sign informed consent.
2. Call study coordinator to register inclusion, check eligibility criteria, and for randomization.

Randomization (1:1)

Arm A:
Surgical exploration
with intention for resection

1:1

Arm B:
MRI-guided SABR
(5 x 10 Gy)

Treatment should start within 2-4 weeks from date of randomization

Follow-up from randomisation

All timings are measured from randomisation

Randomisation	0	QoL	CASTOR	
2 months	2		CASTOR	CT + TM
3 months	3	QoL	CASTOR	
6 months	6	QoL	CASTOR	CT + TM
12 months	12	QoL	CASTOR	CT + TM
18 months	18	QoL	CASTOR	CT + TM
24 months	24	QoL	CASTOR	CT + TM
36 months	36	QoL	CASTOR	CT + TM
48 months	48	QoL	CASTOR	CT + TM
60 months	60	QoL	CASTOR	CT + TM

QoL = Quality-of-life questionnaire

CASTOR = Moment of data registration in Castor

CT + TM CT= CT thorax +abdomen
TM= serum CA 19-9 + CEA

Allocated treatment within 2-4 weeks from randomisation

SAE reporting - mandatory, 0-6 months from randomisation:
The local investigator reports every SAE to the study coordinator within 7 days via preopanc4rct@amsterdamumc.nl + registers SAE in **Castor EDC**.

Prospective data entry in Castor

Arm A:
Intraoperative survey by **surgeon** (same day as operation)

Histopathology survey by **pathologist** (<2 weeks after surgery)

Arm B:
Post-SABR survey by **radiotherapist/ radiation oncologist**

Study coordinator / randomisation / LAPC expert panel:
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