Table 1 – Abbreviated inclusion and exclusion criteria for InPACT

Inclusion criteria

Male, aged ≥18 yr

Histologically proven squamous cell carcinoma of the penis

Stage:

Any T, N1 (ie, a palpable mobile unilateral inguinal lymph node), M0; or

Any T, N2 (ie, palpable mobile multiple or bilateral inguinal lymph nodes), M0; or

Any T, N3 (ie, fixed inguinal nodal mass or any pelvic lymphadenopathy), M0

Measurable disease according to Response Evaluation Criteria in Solid Tumours v.1.1

Eastern Cooperative Oncology Group performance status ≤2

Patient is fit to receive the randomisation options for which he is being considered

Haematological and biochemical parameters within local standards for randomisation options

eGFR >50 ml/min (patients with eGFR <50 ml/min are only eligible for the surgery alone arm or the neoadjuvant chemoradiotherapy arm, and not the neoadjuvant chemotherapy arm)

Willing and able to comply with the follow-up schedule

Able to give written informed consent

Exclusion criteria

Nonsquamous malignancy of the penis

Pure verrucous carcinoma of the penis

Presence of metastatic squamous cell carcinoma of the penis

Previous chemotherapy or chemoradiotherapy outside of the InPACT trial

Concurrent malignancy (other than squamous cell carcinoma or basal cell carcinoma of non-penile skin) that has required surgical or nonsurgical treatment in the last 3 yr

Patients who are sexually active and unwilling to use effective contraception (if they are not already surgically sterile)

eGFR = estimated glomerular filtration rate.

Table 2 – Burden of disease risk stratification for treatment allocation in InPACT-neoadjuvant

Disease burden	Inclusion criteria	GFR (ml/min)	Allocation to trial arms [a]				
			A	A vs B vs C	A vs C	B vs C	C
Low	One mobile LN with no HRF-CT	Any	Trial entry	X	X	X	X
Intermediate	Two ipsilateral mobile LNs with no HRF-CT	≥50	Trial entry	Randomise	X	X	X
		<50	Trial entry	X	Randomise	X	X
High	Bilateral, pelvic, or fixed LNs, or radiological evidence of ≥3 LNs involved or Presence of HRF-CT	≥50	Trial entry [b]	Randomise	X	Randomise	X
		<50	Trial entry [b]		Randomise	X	Trial entry

LN = lymph node; HRF-CT = high-risk features on computed tomography; GFR = estimated glomerular filtration rate.

[a] Arm A = surgery; arm B = neoadjuvant chemotherapy; arm C = neoadjuvant chempradiotherapy. X denotes allocations not permitted in the trial. No cell shading denotes first-choice treatment allocation and shading denotes allocation at investigator discretion.

[b] Not if pelvic LNs involved.