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

Haematologic 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**

Non-squamous 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

<table>
<thead>
<tr>
<th>Disease burden</th>
<th>Inclusion criteria</th>
<th>GFR (ml/min)</th>
<th>Allocation to trial arms a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>One mobile LN with no HRF-CT</td>
<td>Any</td>
<td>Trial entry</td>
</tr>
<tr>
<td>Intermediate</td>
<td>Two ipsilateral mobile LNs with no HRF-CT</td>
<td>≥50</td>
<td>Trial entry</td>
</tr>
<tr>
<td></td>
<td>Bilateral, pelvic, or fixed LNs, or radiological evidence of ≥3 LNs involved or Presence of HRF-CT</td>
<td>&lt;50</td>
<td>Randomise</td>
</tr>
<tr>
<td>High</td>
<td></td>
<td>≥50</td>
<td>Trial entry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&lt;50</td>
<td>Randomise</td>
</tr>
</tbody>
</table>

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 chemoradiotherapy. 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.