NCI National Clinical Trials Network

EA8134/InPACT

ECOG-ACRIN cancer research group
Reshaping the future of patient care

For Patients with Penile Cancer

EA8134 Available Through ECOG-ACRIN Cancer Research Group

InPACT: International Penile Advanced Cancer Trial

Patient Population

See Section 5.0 for Complete Eligibility Details

Inclusion Criteria (InPACT-neoadjuvant):

- Male, aged 18 years or older, PS 0-2
- Histologically–proven squamous cell carcinoma of the penis; Stage any T, N1-3, M0
- InPACT-neoadjuvant only: measureable disease (RECIST 1.1) or, for Arm A: a single, unilateral lymph node that is palpable/radiologically abnormal with histological/ cytological evidence of metastatic involvement
- Fit to receive the randomization options for which he is being considered (i.e., hematology, liver/renal function)
- Nodal disease burden must be assessable

Inclusion Criteria (InPACT-pelvis):

- Has met all criteria for InPACT-neoadjuvant; has completed ILND within arms A/B/C
- No radiological evidence of residual inguinal disease/ pelvic lymphadenopathy on cross-sectional imaging
- Must be at high risk of relapse following ILND

Exclusion Criteria:

- Pure verrucous carcinoma/non-squamous malignancy of the penis; squamous carcinoma of the urethra
- Stage M1; or regionally advanced (N1-3, M0) penile cancer with disease burden that is considered unresectable
- Previous systemic chemotherapy/chemoradiotherapy outside of the InPACT trial; absolute contraindication to chemotherapy (if eligible for that randomization)
- Concurrent malignancy (other than SCC or basal cell carcinoma of non-penile skin) that has required surgical/ non-surgical treatment in the last 3 years
- Sexually active patients unwilling to use effective contraception (if they are not already surgically sterile)

Additional Neoadjuvant Criteria (see Section 5.5):

- Low disease burden: not eligible for the randomized component (go to Arm A); intermediate/high disease burden: suitable to receive neoadjuvant therapy
- A GFR of ≥ 50 ml/min is acceptable for Arm B/C

Additional Pelvis Criteria (refer to Section 5.6)

Treatment Plan

See Section 9.0 for Complete Treatment Details

Patients may receive 1-4 study interventions:

- Inguinal lymph node dissection (ILND);
- Neoadjuvant chemotherapy (followed by ILND);
- Synchronous chemoradiotherapy (in either the neo-adjuvant or adjuvant setting);
- Prophylactic pelvic lymph node dissection (PLND)

Neoadjuvant chemotherapy: paclitaxel, ifosfamide and cisplatin (TIP):

- Paclitaxel 175 mg/m² IV over 3 hours
- Ifosfamide 900 mg/m² IV over 1 hour outpatient; or 1200 mg/m² IV over 2 hours inpatient
- Cisplatin 15 mg/m² IV (outpatient) or 25 mg/m² IV (inpatient) over 1-2 hours

Patients will receive up to 4 cycles (1 cycle= 21 days). Then, they will proceed to therapeutic ILND (to occur 6 -12 weeks after day 1 of the last chemotherapy cycle)

Synchronous chemoradiotherapy with cisplatin may be delivered in the neoadjuvant and the adjuvant setting, subject to patient's treatment allocation, disease burden and GFR status:

- IMRT per protocol; for neoadjuvant treatment, the radiotherapy dose is 45 Gy in 25 fractions over 5 weeks; for adjuvant treatment, see the planning guidance document
- Cisplatin 40 mg/m² weekly

Patients in InPACT-neoadjuvant will proceed to therapeutic ILND upon completion of 5 weeks of chemoradiotherapy (no more than 12 weeks after radiotherapy)

Prophylactic PLND will be performed as a separate procedure after inguinal lymphadenectomy in the majority of patients. It can be performed via infra-umbilical incision, extraperitoneal dissection, or by a minimally-invasive technique (robotic or laparoscopic)

Study Chair:
Steve Nicholson, MD

ECOG-ACRIN Study Chair:
Curtis Pettaway, MD

Patient Enrollment

All Sites: Oncology Patient Enrollment Network (OPEN) https://open.ctsu.org

Protocol Information

ECOG-ACRIN Operations-Boston: 857-504-2900, http://ecog-acrin.org (Member Login)

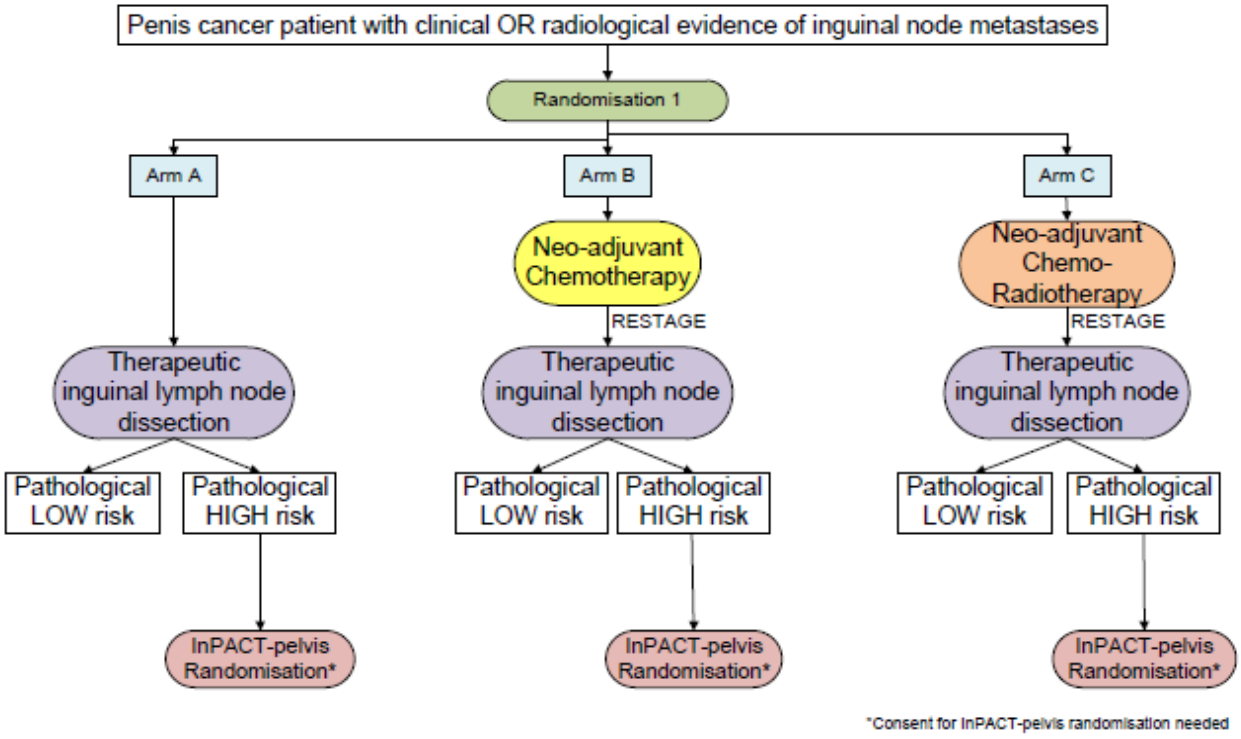
Please Enroll Your Eligible Patients!

EA8134/InPACT

TRIAL SCHEMA

Accrual: 200 patients

InPACT-neoadjuvant



*Consent for InPACT-pelvis randomisation needed

InPACT-pelvis