NCI National Clinical Trials Network

# EA7211/STRASS 2

## For Patients with Retroperitoneal Sarcoma

### EA7211 Available Through ECOG-ACRIN Cancer Research Group

A Randomized Phase III Study of Neoadjuvant Chemotherapy followed by Surgery versus Surgery Alone for Patients with High Risk Retroperitoneal Sarcoma (STRASS 2)

*Sponsored by EORTC and EORTC Soft Tissue and Bone Sarcoma Group (EORTC 1809-STBSG)*

***Please Enroll Your Eligible Patients!***

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***NCTN Study Champions:***
- ***Alliance:*** Chandrajit P. Raut, MD, MSc
- ***NRG:*** Dian Wang, MD
- ***SWOG:*** Lara Davis, MD

## Patient Population

*See protocol Section 4 for complete eligibility criteria*

**Inclusion criteria:**

- ≥ 18 years old, WHO performance status ≤ 2, adequate lab values, ASA score < 3
- Histologically proven primary high risk leiomyosarcoma (LMS) or liposarcoma (LPS) of retroperitoneal space or infra-peritoneal spaces of pelvis
  - ◊ LMS: any grade and size > 5 cm
  - ◊ DDLPS (MDM2 and CDK4 expression on IHC):
    - ⇒ Grade 3, ***or*** Grade 2 with FNCLCC score = 5 and clear necrosis on imaging (whether or not present on the biopsy) or Complexity Index in Sarcomas (CINSARC)-high (high risk gene profile)
- Unifocal tumor; resectable tumor (details per protocol)
- Measurable disease (RECIST 1.1), as confirmed by imaging

**Exclusion criteria:**

- Sarcoma originating from bone structure, abdominal or gynecological viscera; extension through the sciatic notch/ across the diaphragm; metastatic disease
- Tumor grading not assessable from biopsy (except LMS)
- Any previous surgery (excluding diagnostic biopsy), radiotherapy or systemic therapy for the present tumor
- Hypersensitivity to doxorubicin, ifosfamide, dacarbazine, or any of their metabolites/excipients
- Congestive heart failure, angina pectoris, acute inflammatory heart disease, myocardial infarction within 1 year of randomization, uncontrolled arterial hypertension, or uncontrolled cardiac arrhythmia
- Previous treatment with maximum cumulative doses per protocol
- Active and uncontrolled infections (especially urinary tract)
- Inflammation of urinary bladder (interstitial cystitis) and/or obstructions of the urine flow

## Treatment Plan

*See protocol Section 6 for complete treatment details*

- **Standard arm:** large en-bloc curative intent surgery within 4 weeks following randomization
  - ◊ See protocol for details including operability criteria and surgical procedures
- **Experimental arm:** 3 cycles of neoadjuvant chemotherapy starting within 2 weeks from randomization, followed by reassessment of operability and curative intent surgery within 3-6 weeks after Day 1 of last cycle of chemotherapy
  - ◊ High grade LPS: Doxorubicin 75 mg/m² (or the equivalent epirubicin 120 mg/m²) + ifosfamide 9 g/m² Q3weeks
  - ◊ LMS: Doxorubicin 75 mg/m² (or the equivalent epirubicin 120 mg/m²) + dacarbazine 1 g/m² Q3weeks
- Imaging will be performed at Weeks 12, 24, 36 and 48, then every 4 months up to Month 24; after Month 24, every 6 months until recurrence or death
  - ◊ CT thorax abdomen pelvis with IV contrast is preferred; use the same modality throughout
- Follow-up telemedicine visits are permitted; no more than two consecutive (i.e., patients must be seen in person at every third visit, at minimum)

***Note: Some procedures noted in the protocol should only be done as clinically indicated in the US*** *(i.e., LDH [mandatory prior to randomization], CRP, proteinuria, 12–lead ECG, IV pyelogram [done during the baseline CT]/ differential renal isotope scan); see US Appendix Section 5*

***For more guidance on treatment, please see the EA7211 EMR template posted under Protocol Related Documents on CTSU***

**Patient Enrollment (Oncology Patient Enrollment Network [OPEN])**

https://open.ctsu.org/open 1-888-823-5923

**Protocol Information (ECOG-ACRIN Operations – Boston)**

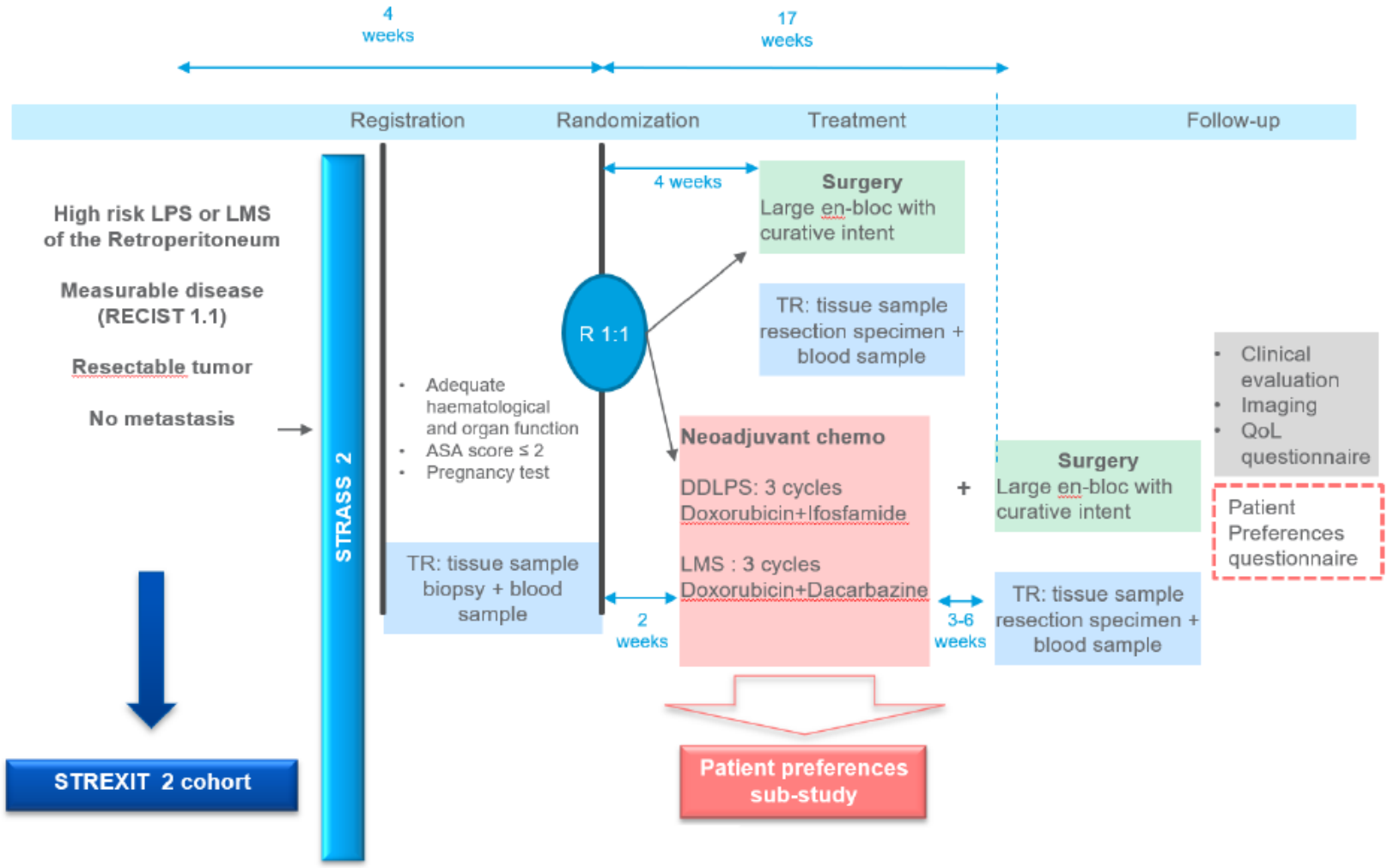
http://ecog-acrin.org (Member Login) 1-857-504-2900

ECOG-ACRIN cancer research group

EORTC European Organisation for Research and Treatment of Cancer — The future of cancer therapy

# EA7211

Figure 1 - Trial design.




**US Accrual Goal: 150**

*Note: US sites will not participate in STREXIT 2, central pathology review submissions, translational research submissions, specimen collection/submissions, QOLs or Geriatric Assessments.*