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)

Patient Population

See Protocol Section 4 for Complete Eligibility Details

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: Grades 2 and 3, of minimum size 5 cm
  - ◊ LPS (diagnosed on IHC, MDM2 and CDK4 expression): Grade 3 DDLPS, ***or*** confirmed grade 2 DDLPS on biopsy only if 1) FNCLCC score = 5 and clear necrosis on imaging (whether or not present on biopsy), or 2) high risk gene profile as determined by the Complexity Index in Sarcomas
- Unifocal tumor; resectable tumor (details per protocol)
- Radiologically measurable disease (RECIST 1.1), as confirmed by imaging within 28 days of randomization

Exclusion criteria:

- Sarcoma originating from bone structure, abdominal or gynecological viscera; metastatic disease
- Extension through the sciatic notch/across the diaphragm
- Tumor grading not assessable from biopsy
- 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
- Active and uncontrolled infections (especially urinary)
- Inflammation of the 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)
- **Experimental arm:** 3 cycles of neoadjuvant chemotherapy starting within 2 weeks from randomization according to histology (high grade LPS/LMS) 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 Q3 weeks
  - ◊ LMS: Doxorubicin 75 mg/m² (or the equivalent epirubicin 120 mg/m²) + dacarbazine 1 g/m² Q3 weeks
- Tumor assessments will be performed every 12 weeks until week 48. Then tumor assessments will be performed every 6 months until progression or death
  - CT thorax abdomen pelvis with IV contrast is preferred; use the same modality throughout the study

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 the CTSU

EORTC Study Coordinator:
Alessandro Gronchi

EORTC Study Co-Coordinator:
Winan Van Houdt

ECOG-ACRIN Study Chair:
Kenneth Cardona, MD

ECOG-ACRIN Study Co-Chair:
Richard F. Riedel, MD

Patient Enrollment

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

Protocol Information

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

Please Enroll Your Eligible Patients!

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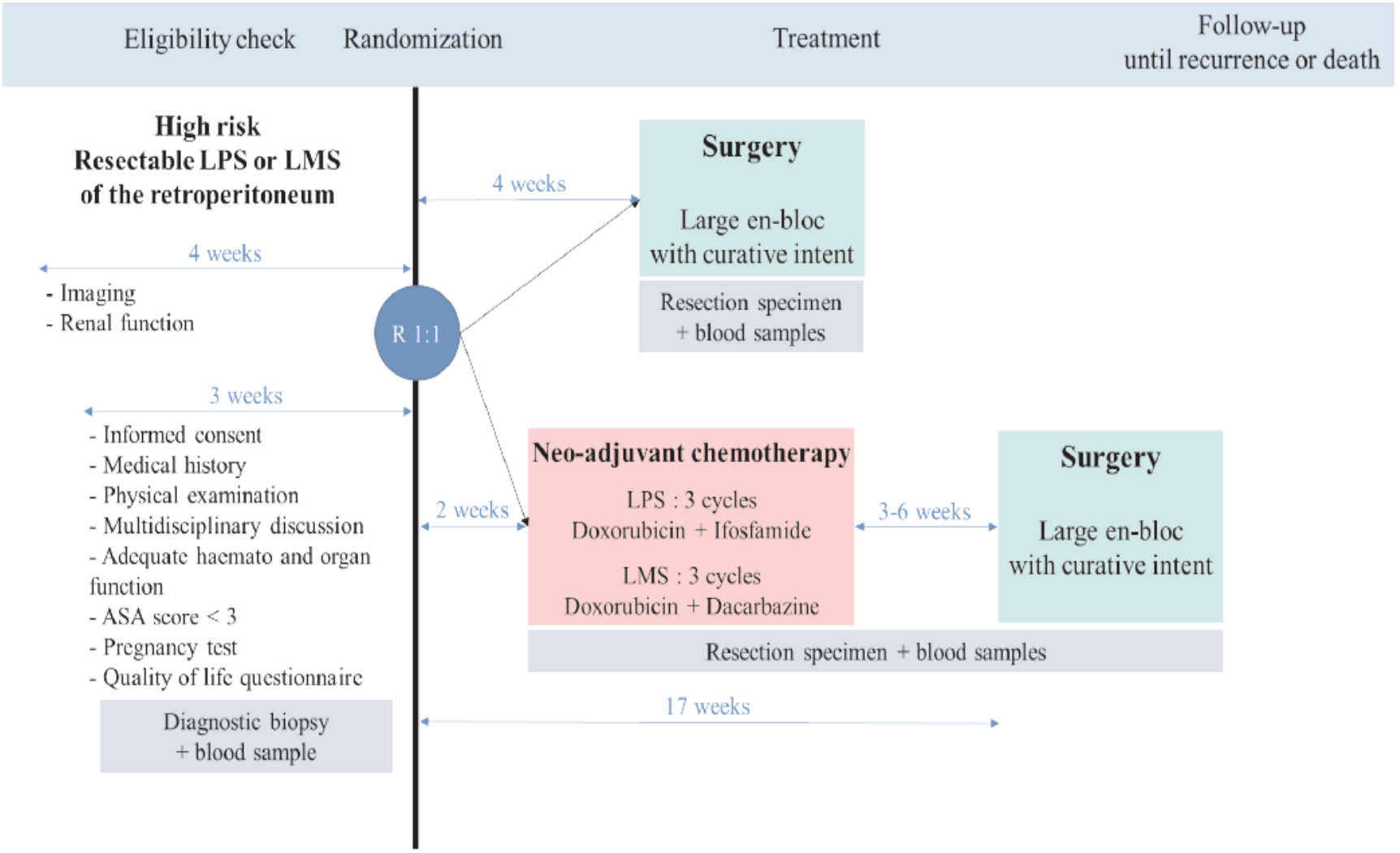
ECOG-ACRIN cancer research group

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

EA7211



Accrual: 250 patients