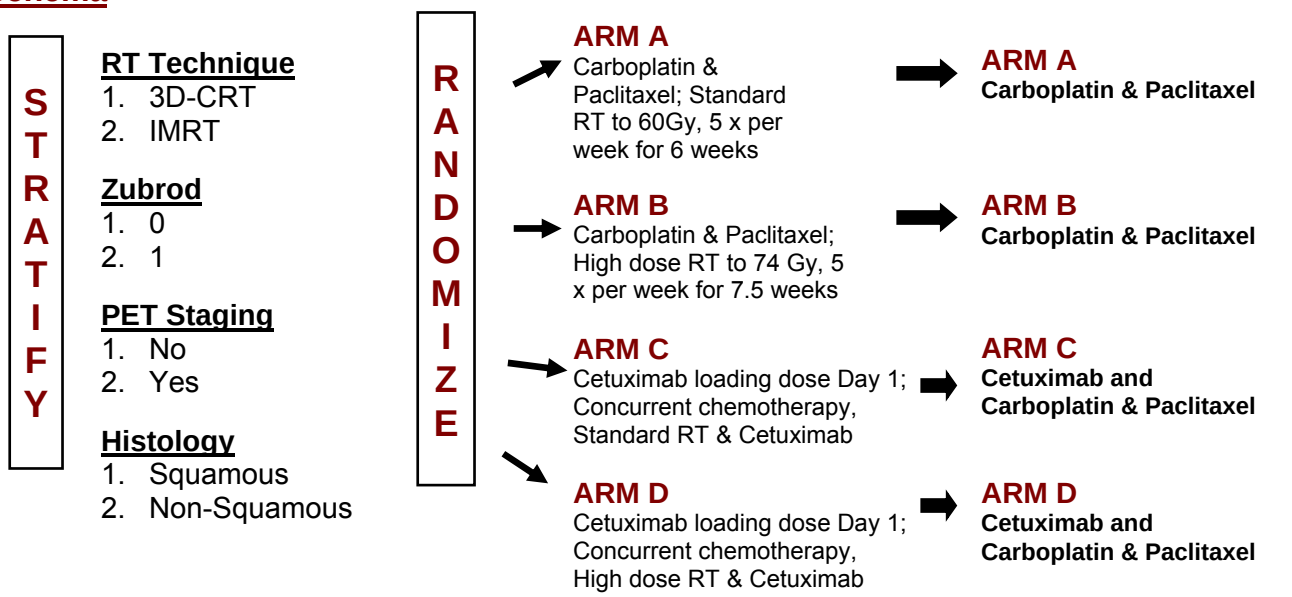
RTOG
RADIATION THERAPY ONCOLOGY GROUP

RTOG 0617 / NCCTG N0628
CALGB 30609 / ECOG R0617

Protocol Summary

A Randomized Phase III Comparison Of Standard Dose (60 Gy) Versus High Dose (74 Gy) Conformal Radiotherapy With Concurrent And Consolidation Carboplatin/Paclitaxel +/- Cetuximab In Patients With Stage IIIA/IIIB Non-Small Cell Lung Cancer

Schema



Patient Population - *See Section 3.0 of Protocol for Complete Eligibility Details*

- Pathologically proven (either histologic or cytologic) diagnosis of Stage IIIA or IIIB non-small cell lung cancer
- Patients must be considered unresectable or inoperable
- Patients must have measurable or evaluable disease
- Zubrod Performance Status 0-1
- Absolute neutrophil count (ANC) ≥ 1,800 cells/mm^3, Platelets ≥ 100,000 cells/mm^3
- Hemoglobin ≥ 10.0 g/dl (Note: The use of transfusion or other intervention to meet Hgb requirement is acceptable)
- Serum creatinine within normal institutional limits or creatinine clearance ≥ 60 ml/min.
- Bilirubin within normal institutional limits
- AST and ALT < 2.5 x the IULN
- No N3 supraclavicular disease
- No greater than minimal, exudative or cytologically positive plural effusions or pancoast tumors

Required Sample Size: **500**

Participating Groups: RTOG, NCCTG, CALGB, ECOG

Principal Investigators:

RTOG: Jeffrey Bradley, MD, 314-362-4633, jbradley@wustl.edu
NCCTG: Steven Schild, MD, 480-301-8000, sschild@mayo.edu
CALGB: Jeff Bogart, MD, 315-464-5276, bogartj@upstae.edu
ECOG: M. Christian Dobelbower, MD, PhD, 205-975-5671, mdobelbower@uabmc.edu

Objectives:

The primary goals of the study is to compare the overall survival of patients treated with high-dose versus standard-dose conformal radiation therapy in the setting of concurrent chemotherapy and to compare the overall survival of patients treated with cetuximab versus those treated without cetuximab in the setting of concurrent chemotherapy. Secondary objectives include: comparing progression-free survival and local-regional tumor control between high-dose and standard radiation therapy and between concurrent cetuximab versus no cetuximab, comparison of the toxicity of high-dose versus standard dose conformal radiation therapy in the setting of concurrent chemotherapy with or without cetuximab, investigation of the prognostic and predictive effects of gross tumor volume on overall survival, correlation of outcomes (survival, toxicity, QOL) with biological parameters and investigation of the associations between EGFR expression and toxicity, response, overall survival and progression-free survival.