

104 Pilot Study To Evaluate The Effect Of Erlotinib Administered Before Surgery In Operable Patients With Squamous Cell Carcinoma Of The Head And Neck (SCCHN).

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Purpose/Objective(s): Strategies for early detection of cellular response to EGFR inhibitors are critical to personalizing therapy for SCCHN. The glycolytic enzymes responsible for uptake of the positron emission tomography (PET) tracer [18F] 2- fluoro-2-deoxy-d-glucose (FDG) are regulated by intermediates of the EGFR pathway such as AKT, mTOR and MAPK. It was hypothesized that the inhibition of these EGFR pathway markers could be read by the 18[F]-FDG uptake by tumor. It is also possible that the EGFR pathway is aberrantly activated in some cancers and that glycolysis and downstream effects are not always linked. Previous in vitro and in vivo studies showed that 18[F]-FDG uptake changes very early in SCCHN tumor models responsive to EGFR inhibition. We developed a pilot clinical protocol to investigate this further in patients with SCCHN. **Materials/Methods:** Patients with operable SCCHN with a window of at least 15 days between the time of initial biopsy and established surgery will receive erlotinib 150 mg/day or 300 mg/day if the patient is actively smoking. Smokers metabolize erlotinib rapidly with an MTD that is twice that of non-smokers. Patients must have additional biopsy tissue for laboratory research studies. 18[F]-FDG PET scan and neck CT with contrast are performed before treatment, 4-6 days through treatment and at the end of erlotinib administration. **Results:** 11 patients have been treated to date with an average of 18.6 days of treatment. Of the 10 evaluable patients, 7 showed partial response (PR) and 3 patients showed stable disease (SD). 8 patients received erlotinib 300 mg. No grade 3 or 4 toxicities. Early (4-6 days)18[F]-FDG PET scans showed a decrease in SUV max to 93.25% +/- 18% in patients with SD and to 51% +/- 22% in patients with PR (defined as at least 20% reduction in maximum diameter). This pilot trial will continue to enroll patients to address the primary laboratory research correlative aim. Pre-and post-treatment tumor tissue is available in all patients. **Conclusions:** Short course treatment with erlotinib in a dose adjusted per smoking status is very active in previously untreated patients with SCCHN. Early changes in the 18[F]-FDG PET scan uptake can be used as a marker predictive of response to EGFR inhibition.