CPH 576C, Applied Biostatistics Analysis Dr Melanie Bell

Project 3, Longitudinal Analysis

This project will use data derived from a phase III randomized controlled trial for advanced lung cancer patients. This was a three arm trial comparing two new Paclitaxel-cisplatin regimens with a traditional etoposide-cisplatin regimen. For this analysis, combine the two experimental therapies, so that comparisons will be between this combined arm and the standard therapy. The data and data dictionary can be downloaded from D2L, and more information about the trial can be found here <http://jco.ascopubs.org/content/18/3/623.full.pdf>. A few things that are not obvious from the data dictionary: funo stands for follow-up number, but funo = 1 means baseline. ECOGPS stands for Eastern Co-operative Oncology Group performance status and is a physician rating which ranges from 0 (asymptomatic) to 5 (dead). CRPR stands for complete or partial remission. Cycles means chemotherapy cycles. PD is a type of adjunct therapy.

We will be using data on health related quality of life (QOL). Our objectives are to describe QoL over time for each of the two arms and to compare QoL between the two arms. QoL was measured using the trial outcome index (TOI) of the Functional Assessment of Cancer Therapy – Lung, or FACT-L. The FACT-L is a validated questionnaire with domains of functional, physical, social, and emotional well-being, in addition to a set of lung cancer specific symptom questions (additional concerns). The TOI is the sum of the physical, functional and symptoms scores, scaled to a range of 0-100, with higher values indicating greater QoL.

Please give the following estimates :

* Means and SDs at each timepoint
* Differences between the intervention arms and control at each post-baseline timepoint, and 95% CI.
* Changes from baseline at each timepoint and 95% CI, by arm.
* Difference in the average of the post-baseline assessments and 95% CI, between the arms. SAS users, you may have to use the divisor option in your estimate statement.

There is considerable missing data, including some due to death. Thus your report should include a rigorous approach to handling missing data.

Please include a good graph(s) to describe QoL over time.