

Protocol title: A feasibility study of Chinese herbs to manage cancer-related symptoms in patients with advanced non-small-cell- lung cancer

NCT 02331394

Date of the SAP 15-Nov-2015

Statistical Analysis Plan

- Data will be analyzed using IBM SPSS statistics software (Version 20 for Windows).
- Simple descriptive statistics (percent, means with standard deviation; proportions) will be used to summarize the data.
- The Functional Assessment of Cancer Therapy-Lung (FACT-L) Quality of Life (QOL) questionnaire will be reported as:
 1. FACT -L total score
 2. The scores of the five individual subscales
 3. The composite Trial Outcome index (TOI), which is the sum of the functional and physical well-being and the lung cancer symptoms subscales.
- A Clinically Meaningful Change (CMC) in symptom scores is defined as a 6-point change in TOI.
- Two points difference will be used as a CMC for ESAS symptoms.
- Comparisons of repeated measures will be made using paired sample *t* test, which will compare subjects data at 2 different times: baseline and end of the study.
- A P value of 0.05 will be considered statistically significant.