6.0 Statistical Considerations for CCCG-LBL-2016

Primary aims:

- To determine the 3-year EFS (event free survival) in all evaluable patients with newly diagnosed lymphoblastic lymphoma enrolled in the study compared with the historical study
- To describe the 3-year EFS in high-risk group

Secondary aims:

- To describe the 3-year OS (overall survival) in all evaluable patients with newly diagnosed lymphoblastic lymphoma enrolled in the study

Enrollment:

It is expected that approximately 150 patients will be recruited to the study across the 8 sites (Table) over 5 years. The 8 sites, SCMC, TJ, HX, QL, TJZ, SZ, NJ and XY will contribute approximately 36%, 8%, 8%, 11%, 15%, 3%, 11% and 8% of patients respectively. The estimates are based on recent accrual numbers from each hospital.

Groups	Estimated new LBL cases in 8 sites (2016-2020)
Low Risk	10
Intermediate Risk	102
High Risk	37
Total	150

The primary endpoint will be analyzed using a one-sided 95% CI for the difference of probability EFS (pEFS) at 3 years between the test group and the historical group. The expected number of patients is 150 in the target group of CCCG-LBL-2016 and 96 in the historical group （retrospective study, combined treatment protocols BFM90/95, SCMC2007, SCMC-2011 and CCCG-LBL-2010）. With these expected numbers of patients, the power to prove noninferiority of treatment was estimated to be 0.70 if pEFS is 0.65 in the control group (type I error = 5%)