

Official title: Persistent Lymphopenia in Liver Transplantation and Its Molecular Insights for Hepatocellular Carcinoma

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Study Protocol and Statistical Analysis Plan:

The subjects of this study were HCC patients with low lymphocytes (experimental group) and normal lymphocytes (control group). The sample type was blood and was divided into two parts: retrospective and prospective.

The source of retrospective blood (including serum, plasma or white blood cells) is to apply for specimens from tissue banks and biobank of Kaohsiung Chang Gung Memorial Hospital (KCGMH). At the same time, the patient's medical record, such as gender, age, lymph node, etc. will also be requested. The number of cells, total number of white blood cells, survival, recurrence, biochemical test data and other information are collected.

Prospective blood is newly collected. The source is that during the patient's treatment, about 20ml blood is drawn during routine examinations. This will not increase the burden on the patient. We will ask the patient one week before collecting the specimen if he is willing to provide the specimen for research purposes, and we guarantee that his personal information and privacy will not be disclosed. Unused specimens will be destroyed after the research is completed.

We will perform retrospective analysis at first. 145 HCC patients will be divided into 2 groups with or without lymphopenia, followed by comparing the effects of clinical data between them. Blood samples will be collected to analyze the impact and expression of protein, gene and microRNA (miRNA). Next Generation Sequencing (NGS) will be applied to find unknown important factors. In prospective study, 20 lymphopenia and 25 non-lymphopenia HCC recipients were enrolled, and a phenotypic analysis of peripheral blood lymphocytes was performed using multiparameter flow cytometry to identify the major immune cell subsets and validate previous results.

One-way analysis of variance will be used with Bonferroni's post hoc analysis for comparison between multiple groups. Student's t test will be used for comparison of continuous data between two groups while chi-square for discrete data. Significance is defined as $P < 0.05$.