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Phase II clinical trial on synchronous livin peptide-loaded dendritic cell vaccine and radiotherapy in advanced NSCLC patients

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Abstract

Background: Our previous study (Sun JG, et al. Cancer Biother Radiopharm. 2011) demonstrated that Livin, an inhibitor of apoptosis proteins (IAP), could be a radio sensitizer in non-small cell lung cancer (NSCLC) and a good molecular target for autologous dendritic cell (DC) immunotherapy which was approved as Class III medical technology by General Logistics Department of PLA. Thus we carried out a phase II clinical trial on synchronous Livin peptide-loaded DC vaccine and radiotherapy in advanced NSCLC patients, which was registered at Chinese Clinical Trial Registry (ChiCTR-12002369, http://www.chictr.org/en/).

Objective: To explore the efficacy, safety, and immunologic effect of synchronous Livin peptide-loaded DC vaccine and radiotherapy in NSCLC patients.

Methods: By Dec 2014, 118 advanced NSCLC patients who received 3-4 cycles of chemotherapy will be enrolled , of which 78 cases given radiotherapy alone (control group) and 40 cases given extra Livin peptide-loaded DC therapy synchronously (test group). Three HLA restricted epitope peptides of Livin, KWFPSCQFLL (HLA-A24), RLQEERTCKV (HLA-A2) and RLWEERTCK (HLA-A3), were synthesized. Radiotherapy in the control group was executed 2 Gy per fraction, 5 fraction per week to a total dose of 60-66 Gy. In addition to undergoing the same dose of radiotherapy, DC loaded with Livin peptides was subcutaneously injected in the test group every week for 4-5 weeks starting from the 6^{th} irradiation. The primary endpoint was progression-free survival (PFS), and secondary endpoints were response rate (RR), side effects, immunologic effect and performance status (PS).

Results: By May 2013, 98 cases have been enrolled consisting of 68 cases in the control group and 30 cases in the test group. 85 cases have finished the treatment with 65 cases in the control group and 20 cases in the test group. The analysis of raw data showed that the objective response rate (ORR) in the test and control groups was 80% and 55%, respectively; the grade 2 and above radiation pneumonitis (RP) in the test and control groups was 13.5% and 21%, respectively, and the immunologic effect (IL-2, IFN, CD4/CD8, etc) was stronger in the test group than in the control group. No unaccepted side effects were observed in the test group.

Conclusions: Preliminary results indicate certain advantage of Livin peptide-loaded DC plus radiotherapy over radiotherapy alone in advanced NSCLC patients. The conclusions will be made after the completion of enrollment and follow-up.

Biography

Jian-Guo Sun received his PhD in oncology in 2004 from Third Military Medical University, China. He is an associate professor and vice director of Cancer Institute of Xin-Qiao Hospital. He is a member of West China Radiotherapy Association, a winner of West China Talent Project, and a visiting scholar in the Department of Radiation Oncology, Stanford University. Over the past 17 years, he has been a physician and an oncology researcher, who has published about 20 articles in international journals. His current research focuses on the influence of circulating cells on revascularization and regrowth of lung cancer cells after radiation.