A phase II study of Tg4010 (Mva-Muc1-Il2) in association with chemotherapy in patients with stage III/IV Non-small cell lung cancer

JournalArticle (Originalarbeit in einer wissenschaftlichen Zeitschrift)

ID 1193257
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Year 2008
Title A phase II study of Tg4010 (Mva-Muc1-Il2) in association with chemotherapy in patients with stage III/IV Non-small cell lung cancer
Journal Journal of thoracic oncology
Volume 3
Number 7
Pages / **Article-Number** 735-744
TG4010 is a recombinant viral vector expressing both the tumor-associated antigen MUC1 and Interleukine-2. This vector is based on the modified virus of Ankara, a significantly attenuated strain of vaccinia virus. TG4010 has been designed to induce or amplify a cellular immune response directed against tumor cells expressing MUC1. A multicenter, randomized phase II study has explored two schedules of the combination of TG4010 with first line chemotherapy in patients with stage IIIB/IV non-small cell lung cancer. In Arm 1, TG4010 was combined upfront with cisplatin (100 mg/m day 1) and vinorelbine (25 mg/m day 1 and day 8). In Arm 2, patients were treated with TG4010 monotherapy until disease progression, followed by TG4010 plus the same chemotherapy as in Arm1. Response rate was evaluated according to RECIST. Median time to progression and median overall survival were calculated according to the Kaplan-Meier method. Sixty-five patients were enrolled, 44 in Arm 1 and 21 in Arm 2, in accordance with the two stage Simon design of the statistical plan. In Arm 1, partial response was observed in 13 patients out of 37 evaluable patients (29.5% of the intent to treat population, 35.1% of the evaluable patients). In Arm 2, two patients experienced stable disease for more than 6 months with TG4010 alone (up to 211 days), in the subsequent combination with chemotherapy, one complete and one partial response were observed out of 14 evaluable patients. Arm 2 did not meet the criteria for moving forward to second stage. The median time to progression was 4.8 months for Arm 1. The median overall survival was 12.7 months for Arm 1 and 14.9 for Arm 2. One year survival rate was 53% for Arm 1 and 60% for Arm 2. TG4010 was well tolerated, mild to moderate injection site reactions, flu-like symptoms, and fatigue being the most frequent adverse reactions. A MUC1-specific cellular immune response was observed in lymphocyte samples from all responding patients evaluable for immunology. The combination of TG4010 with standard chemotherapy in advanced non-small cell lung cancer is feasible and shows encouraging results. A randomized study evaluating the addition of TG4010 to first line chemotherapy in this population is in progress.
Publisher Lippincott Williams & Wilkins
ISSN/ISBN 1556-0864 ; 1556-1380
edoc-URL https://edoc.unibas.ch/63181/
Full Text on edoc No;
Digital Object Identifier DOI 10.1097/JTO.0b013e31817c6b4f

PubMed ID http://www.ncbi.nlm.nih.gov/pubmed/18594319