Clinical BNCT Trials in Sweden

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Introduction

A BNCT facility has been installed at the 1 MW R2-0 research reactor at Studsvik, Sweden. The clinical neutron is obtained from a filter/moderator system that allows easy variation of the neutron spectrum from the thermal to the epithermal energy range. Clinical BNCT trials were initiated in March 2001 and, as of September 2003, a total of 40 patients have been treated.

Phase II trial of BNCT as a primary radiation treatment for glioblastoma multiforme

Thirty glioblastoma multiforme (GBM) patients were included in the study. Boronophenyalanine (BPA) was administered by a 6-hour i.v. infusion to a total dose of 900 mg/kg body weight. Based on the results of previous BNCT studies, the peak and average brain doses were kept below 15 Gy(W) and 6 Gy(W), respectively.

The applied infusion protocol resulted in a significant increase of boron concentration in the blood at the time of irradiation. No serious BNCT-related acute toxicities have been observed. As of September, 2003, the median survival time (MST) of the whole group has not been reached yet but, for the first group of 14 patients (of which 9, 2, and 3 were of the RTOG prognostic group V, IV, and III, respectively) with follow-up time over 24 moths, MST was 16.6 months and the one year survival was 79%.

Phase II trial of BNCT for recurrent GBM

Six patients have been treated according to the current protocol. Afore mentioned BPA doses were given. Maximum radiation doses to the normal brain were adjusted according to the radiation dose given at the primary conventional treatment and the time period from its completion. The treatment was well tolerated. Two of those patients are still alive at 2.5 and 11 months post-BNCT, other deceased at 4, 5, 6.5 and 7 months post-BNCT.

Phase III randomized trial of BNCT as a primary radiation treatment for GBM

The results of our previous protocol for primary GBM are encouraging enough to warrant a Phase III, randomized trial where BNCT will be compared to conventional radiation therapy as a primary radiation treatment for GBM. The protocol is currently under preparation and will be activated at the beginning of 2004.

Phase I/II trial of BNCT for metastasis to the liver

Inspired by the two successful treatments of colon cancer metastases to the liver at Pavia, Italy a protocol for BNCT treatment of explanted livers with metastatic tumors is currently under development in collaboration with a surgery group specialized in liver transplantation at the Huddinge University Hospital in Stockholm.