

Clinical Trial of Cancer Therapy with Heavy Ions at Heavy Ion Research Facility in Lanzhou (HIRFL)

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With collaborative efforts of scientists from the Institute of Modern Physics (IMP), Chinese Academy of Sciences and hospitals in Gansu, initial clinical trial on cancer therapy with heavy ion has been successfully carried out in China.

From November 2006 to August 2007, 36 patients with superficially-placed tumors were treated with carbon ions at Heavy Ion Research Facility in Lanzhou (HIRFL) within four beam time blocks of 6-11 days, collaborating with the General Hospital of Lanzhou Command in Lanzhou, Gansu.

Patients and Methods: There were 36 patients (27 males and 9 females) with superficially-placed tumors (squamous cell carcinoma of the skin, basal cell carcinoma of the skin, malignant skin melanoma, sarcoma, lymphoma, breast cancer, metastatic lymph nodes of carcinomas and other skin lesions). The tumors were less than 2.1 cm deep to the skin surface. All patients had histological confirmation of their tumors. Karnofsky Performance Scale (KPS) of all patients was more than 70. The majority of patients with failures or recurrences of conventional therapies. Median age at the time of radiotherapy (RT) was 55.3 years (range 5–85 years). Patients were immobilized with a vacuum cushion or a head mask and irradiated by carbon ion beams with energy 80-100 MeV/u at spread-out Bragg peak field generated from HIRFL, with two and three-dimensional conformal irradiation methods. Target volume was defined by physical palpation [ultrasonography and Computerized tomography (CT), for some cases]. The clinical target volume (CTV) was defined as the gross total volume GTV with a 0.5-1.0cm margin axially. Field placement for radiation treatment planning was done based on the surface markings. RBE of 2.5-3 within the target volume, and 40–70.4 GyE with a weekly fractionation of $7 \times 3-15$ GyE/fraction were used in the trial. Patients had follow-up examinations performed 1 month after treatment, in 1 or 2 months for the first 6 months, and 3-6 month intervals thereafter. Local control rates were estimated according to WHO criteria. The evaluation included a physical examination (ultrasonography and CT, for some cases) and a complete blood count. Acute and late side effects were scored according to the Common Toxicity Criteria (CTC). Reactions occurring during RT or within the first 3 months after RT were scored as acute reactions.

Results: 34 patients were followed up (ranging from 1-10 months) and 2 were lost to follow-up. The tumors responded very well to the treatment in all patients. The tumor volumes started to regress during the RT or at the end of the RT, and up to 3-6 months, majority of tumors disappeared completely or almost. So far, no severe side-effects and no local recurrence within the treated volume have been observed. Up to data, all patients are alive.

Conclusions: The data demonstrated that heavy ion radiotherapy for patients with shallow-seated tumors is clinically effective and safe, especially for patients with failures or recurrences of conventional therapies.