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By M. Kligerman

RESEARCH PROPOSAL

Los Alamos Meson Physics Facility

Pion Clinical Trials

M. M. Kligerman, Spokesman

Participants and Institutions

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SUMMARY OF EXPERIMENT

To conduct, in accordance with the requirements of U. S. Department of Health, Education and Welfare and University of New Mexico guidelines for research involving human subjects, the necessary studies required to evaluate the efficacy and potential benefit of negative pi mesons (pions) in treatment of advanced tumors, as follows:

1. Human radiobiology studies to establish the response of critical normal structures surrounding metastatic lesions to low doses of pions and control x-radiation,
2. Pilot studies to establish the response of primary tumors and surrounding normal structures to palliative doses of pions and control x-radiation, and
3. Phase III studies to establish the response of primary tumors and surrounding normal structures to curative doses of pions and control x-radiation.

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PROPOSAL INFORMATION

Beam area: A East

Secondary channel: Biomedical channel

Beam requirements: Therapy Π^- beams

Primary beam requirements: $> 20 \mu\text{A}$

Running time required (per year):

Installation: 1000 hrs

Tune-up : 100 hrs

Data runs : 1400 hrs

Scheduling: To be determined

Major LAMPF apparatus required: Collimators, range shifter, and other beam shaping equipment

Shielding and enclosures required: None

Special services required: Maximum beam availability

Space required: As available

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EXPERIMENT #275

PION CLINICAL TRIALS

Spokesman: M. M. Kligerman

Objectives:

To conduct, in accordance with the requirements of U. S. Department of Health, Education and Welfare and University of New Mexico guidelines for research involving human subjects, the necessary studies required to evaluate the efficacy and potential benefit of negative pi mesons (pions) in treatment of advanced tumors, as follows:

1. Human radiobiology studies to establish the response of critical normal structures surrounding metastatic lesions to low doses of pions and control x-radiation,
2. Pilot studies to establish the response of primary tumors and surrounding normal structures to palliative doses of pions and control x-radiation, and
3. Phase III studies to establish the response of primary tumors and surrounding normal structures to curative doses of pions and control x-radiation.

Project Description:

The first human radiobiology studies were conducted at LAMPF between October 21, 1974 and December 19, 1974. Data from these tests were analyzed to determine relative biological effectiveness of the pion beam as compared with 140 kv x-rays, in terms of response of normal tissues surrounding and underlying tumor nodules metastasized to the skin. An optical density measurement technique, applied to photographs of the irradiated areas, yielded an RBE for skin erythema of 1.43 at an optical density of 0.23. An attempt was made to assess intermediate-term reaction on tissue specimens taken at autopsy, using the quantitative histologic method of Chalkley counts. No significant differences were apparent among untreated skin, x-ray-treated skin, or pion-treated skin at five months after treatment.

After the biomedical pion channel is reactivated, initial physics experiments are undertaken, and biology studies with the pion beam resume, the skin experiments will be repeated and tests will begin with metastatic lesions to the head and neck. These will be followed by studies with pulmonary nodules and lesions of the rectum and uterine cervix, as the final series of human radiobiology studies leading to the start of pilot studies.

Pilot trials will be instituted with primary tumors of those organ sites which have been determined potentially most amenable to pion therapy. These organ sites were identified by the Committee on Human Trials of Pion Radiotherapy, UNM/LASL, an advisory committee consisting of some 20 radiation therapists, physicists, radiobiologists, and other physicians and scientists from throughout the nation. Since 1972, this committee has participated in planning for the pion clinical trials and design of protocols and consent forms.

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patients from their institutions for participation in the pion clinical trials. Tumors of the following anatomic sites will be acceptable for the pilot trials and ultimately the Phase III studies using curative dose levels: brain (gliomas), oral cavity, hypopharynx, oropharynx, larynx, thoracic esophagus, lung (superior sulcus), stomach, pancreas, bladder, prostate, uterine cervix, rectum, and extremities (osteogenic sarcoma).

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