

RADIATION THERAPY ONCOLOGY GROUP
 RTOG 79-24

EVALUATION OF RADIOBIOLOGICAL EFFECTS OF
 NEGATIVE PI MESONS ON MISCELLANEOUS METASTATIC LESIONS

Protocol for Human Radiobiology Studies of
 Pi Meson Radiation Therapy at
 University of New Mexico/Los Alamos Scientific Laboratory

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**EVALUATION OF RADIOBIOLOGICAL EFFECTS OF
NEGATIVE PI MESONS ON MISCELLANEOUS METASTATIC LESIONS**

SCHEMA

Eligible Patients: Patients with metastatic lesions originating from biopsy-proven solid tumors, whose projected survival is at least three months

Treatment:

Non-randomized Negative Pi Meson Radiotherapy

Endpoints:

**Tumor regression and time to recurrence
Evaluation of tissue tolerance for pion radiotherapy
Quality and length of survival
Adequacy of tumor localization, treatment planning,
and inhomogeneity correction**

1.0 INTRODUCTION

The rationale for pion radiotherapy is primarily related to two factors: (1) a different biological response in the stopping region of the pion beam from that seen in conventional radiation, and (2) the capability for localizing this differential response within the target volume, largely sparing normal surrounding tissues.

With high-linear-energy-transfer (high-LET) radiation (for example, neutrons, pions, and heavy ions), there is increased irreparable damage of critical molecules (i.e., double-strand breaks in DNA), as compared to the type of damage cause by low-LET radiation (e.g., x-rays, gamma rays of cobalt, electrons, and protons). In addition, cells exposed to low-LET radiation exhibit up to three times more resistance to injury if they are not well oxygenated. Thus, hypoxic cells, large numbers of which are usually present in tumors, are less sensitive to damage than are well oxygenated cells of the tumor and the surrounding normal tissue. The dense ionization of high-LET radiation may overcome the protective effect of hypoxia, killing those cells almost as effectively as well-oxygenated cells. Further, cells are more resistant to low-LET radiation in certain phases of the cell cycle than in others. High-LET radiation reduces differences in cellular sensitivity due to cell cycle variations.

Heavy charged particles, such as pions and heavy ions, distribute their dose with a Bragg peak, a region of intense radiation which can be located in the tumor volume.

Pions have the advantages of both high-LET and low-LET radiation, because they deposit low-LET radiation as they pass through tissue (plateau region), but produce a high-LET component in the stopping (tumor) region. Due to their negative charge, the stopping pions are absorbed by the positively charged nuclei of oxygen, carbon, and nitrogen atoms. This excess energy makes the nuclei unstable and they disintegrate, producing neutrons, protons, deuterons,

tritons, alpha particles, and heavy ions. These events increase the total dose in the pion stopping region and alter the biological effectiveness of the dose in that region because of the dense ionization produced mainly by the alpha particles, heavy ions, and neutrons.

Phase II trials are proposed to study the efficacy of pion radiotherapy in improving local control and, thus, potentially survival for patients with a variety of large solitary metastatic neoplasms, and to assess acute and chronic normal tissue injury associated with such treatment.

Patients with lesions amenable to treatment with conventional radiotherapy, surgery and/or chemotherapy with an anticipated five-year survival rate greater than approximately 40% would be excluded. Patients must be between 18 and 75 years of age and have a Karnofsky status of 60 or greater.

1.1 Summary of the Study.

This is a non-randomized pilot study to evaluate response to pion radiotherapy of miscellaneous metastatic lesions originating from any type of solid tumor. The study of local control as well as tissue tolerances will be the prime goal of this protocol. Additional valuable information will be gained regarding further refinement of techniques of treatment planning, patient set-up and immobilization, assessment of tissue inhomogeneities, and other technical aspects of pion therapy.

Patients previously treated with chemotherapy but not demonstrating objective response will be eligible provided they have not received previous radiotherapy to the area and have a life expectancy of at least three months.

2.0 OBJECTIVES

- 2.1 To evaluate tumor response to pion radiation.
- 2.2 To evaluate normal tissue response and tolerance to multi-fraction pion therapy.

- 2.3 To evaluate important aspects of treatment planning and technical aspects of delivering the radiation (including inhomogeneity corrections) in an attempt to maximize the therapeutic ratio by minimizing the normal tissue volume to be irradiated.

3.0 ELIGIBILITY CRITERIA

3.1 Conditions of Eligibility.

The following conditions must be met before a patient can be admitted to the study:

- 3.1.1 Biopsy-proven malignancy.
- 3.1.2 Metastatic lesion originating from any solid tumor.
- 3.1.3 Patient age between 18 and 75.
- 3.1.4 Little or no chance of cure with conventional therapy.
- 3.1.5 Understanding by the patient of the provisions of the study and voluntary informed consent to participate in the study.
- 3.1.6 Karnofsky status \geq 60.

3.2 Conditions of Ineligibility.

- 3.2.1 Moderate to high chance of cure by other treatment modalities.
- 3.2.2 Previous radiotherapy to site.
- 3.2.3 Ongoing chemotherapy.
- 3.2.4 Life expectancy less than three months or Karnofsky status of less than 60.
- 3.2.5 Active uncontrollable infection in area of irradiation.
- 3.2.6 Medical, psychological or other contraindication to proposed treatment. Age $<$ 18 and $>$ 75 years.

4.0 PRETREATMENT EVALUATION

Pretreatment evaluation will be performed at the University of New Mexico Cancer Research and Treatment Center (CRTC) or by the referring physician at another institution, with findings verified and studies augmented as required by the CRTC study team. The evaluation will include:

- 4.1 Medical history.
- 4.2 Physical examination.
- 4.3 Laboratory tests.
 - 4.3.1 CBC (including differential)
 - 4.3.2 Platelet count
 - 4.3.3 Urinalysis
 - 4.3.4 Serum chemistry profile
 - 4.3.5 Others as indicated
- 4.4 Chest x-ray, tomograms, ultrasound, radionuclide studies, CT scans and others as indicated, particularly if tumor is in close proximity to bone.
- 4.5 Staging procedures as indicated.
- 4.6 An ophthalmologic examination to assess lens opacity (to be performed upon admission to the study).

5.0 ADMISSION TO STUDY

Any patient who meets the require eligibility and pretreatment evaluation criteria will be admitted to the protocol for pion radiotherapy at LAMPF. The following records will be generated by the study team and participating institutions for storage, retrieval and analysis.

1. Patient eligibility form.
2. Pretreatment evaluation form. This form, documenting the history and physical information, laboratory tests and special studies including surgery, will be submitted on those patients referred for treatment.
3. Study entrance form (patient name, address, referring institution, referring physician, etc.)
4. Patient consent form.

A study case number will be assigned to each patient by RTOG Headquarters.

6.0 TREATMENT

All patients will receive non-randomized pion therapy at the Clinton P. Anderson Meson Physics Facility (LAMPF) in Los Alamos, New Mexico, either alone or as a planned boost in conjunction with conventional radiotherapy. Pion doses are based upon previous experience with pion irradiation of various human tumors¹ and for representative sites are outlined below.

Current Treatment Policy

<u>Site</u>	<u>Maximum Dose (Peak Pion Rad)</u>	<u>Minimum Dose (Peak Pion Rad)</u>	<u>Fractions</u>	<u>Days</u>
Pelvis	4500	3600	36	50
Head & Neck*	4500	3600	36	50
Brain				
Whole	2750	2200	22	32
Cone-down	4500	3600	36	50
Pancreas**				
Whole	2400	1920	24	35
Cone-down	3840	3072	24	35

*Boost fields treated to 5000 peak pion cGy (rad) maximum

**Combined with planned external beam conventional therapy

Variations in total dose in the range of $\pm 10\%$ about the above doses will be explored to further evaluate tumor response and normal tissue tolerance. Doses in this range will be considered definitive and will be combined with other conventional therapy as outlined in Section 10.0 Additional Therapy, below.

Planned combinations of conventional radiation therapy with cone-down pion boost therapy will be applied in selected situations based upon previous experience regarding normal tissue tolerance in patients receiving pions alone. The estimated biological equivalent of combined pion and conventional treatment will not exceed that recognized as tolerance for pion or conventional therapy alone.

Treatment methods will be those developed previously for pion therapy with the fixed vertical beam at LAMPF with appropriate modifications and improvements consistent with improved techniques.² Single or multiple port therapy with or without cone-down therapy will be applied on an individualized basis to maximize normal tissue sparing and to accommodate particular difficulties with patient positioning or disease site.

Treatment planning will be performed by computerized calculation from CT data of necessary compensation for body and tumor contours and tissue inhomogeneities.³ Verification of treatment volumes will be accomplished by simulation using orthodiagraphic scanning⁴ and routine in vivo dosimetry.

7.0 ENDPOINTS

- 7.1 Tumor regression and time to recurrence.
- 7.2 Evaluation of tissue tolerances for pion radiotherapy.
- 7.3 Quality and length of survival.
- 7.4 Adequacy of tumor localization, treatment planning and inhomogeneity correction.

8.0 FOLLOW-UP SCHEDULE

8.1 Follow-Up Plan and Schedules.

The referring physician will be encouraged to see the patient in accordance with his customary schedule.

The patient will be seen at the Cancer Research and Treatment Center at one month after treatment, then every three months for 12 months counting from day 1, and semi-annually thereafter until death occurs or survival reaches five years. If the patient cannot return to the CRTC, arrangements will be made to have him examined at another hospital by his referring physician and preferably his radiotherapist and a report of this examination submitted to the CRTC.

8.2 Follow-Up Information.

The following information will be recorded on the follow-up forms at each visit:

8.2.1 Brief interval history related to disease.

8.2.2 Physical examination:

Weight, blood pressure

Temperature

Appropriate aspects of physical examination

Regression of palpable or visible tumor

8.2.3 Laboratory tests and routine x-rays; appropriate studies as indicated.

8.2.4 Specific diagnostic studies, or studies which gave the most reliable information regarding the initial extent of tumor will be repeated at periodic intervals.

8.2.5 Complications of treatment.

8.2.6 Recording and scoring of late reactions and pathologic studies by re-biopsy/autopsy as indicated.

8.2.7 Ophthalmologic exam to assess lens opacity (annually).

8.3 Study Parameters.

Parameters to be recorded throughout the study include:

8.3.1 Degree and time of regression and regrowth.

8.3.2 Assessment of acute radiation effects.

8.3.3 Assessment of long-term radiation effects.

Summary of Study Parameters

	<u>Pretreatment</u>	<u>Follow-Up</u>
History and Physical	x	x
Performance Status (Karnofsky)	x	x
CBC, Differential, Platelet Count	x	x ^a
Chemistry Profile	x	x ^a
Urinalysis	x	
Diagnostic (radiographs, ultrasound, nuclear scans)	x ^a	x ^a
Staging/Localization Procedures	x ^a	
Ophthalmologic Exam	x	x ^b

a - As Indicated

b - Yearly

9.0 ADDITIONAL THERAPY

Subsequent therapy should proceed at the discretion of the patient's responsible physician. The patient or physician will notify the investigator of any treatment instituted that has not been prescribed by the investigator.

10.0 PATHOLOGY

10.1 Initial Surgical (Biopsy) Specimens.

Representative slides and copies of biopsy reports will be submitted to the study center and reviewed by the study pathologists. Copies of the reports from the study pathologists will be forwarded to the referring and/or follow-up physician.

10.2 Subsequent Surgical Specimens.

Any tissue surgically removed from anatomic sites will be examined by pathologists at the participating institution where surgery was performed. Appropriate microscopic slides and pathologic reports will be forwarded to the study center for review by the study pathologists.

10.3 Autopsies.

Autopsies are strongly urged on all study patients by pathologists at the participating institutions. Post-mortem

studies should include a description of irradiated tissues and the character and extent of any persistent, recurrent or metastatic tumor. Autopsy reports and representative microscopic slides will be forwarded to the study center for review by the study pathologists.

11.0 FORMS

Two copies of each study form must be submitted to RTOG Headquarters. Data will be recorded on standard forms to be supplied to participating institutions by RTOG Headquarters.

- a. Photocopy of patient consent form.
- b. Patient eligibility form.
- c. Pretreatment evaluation form.
- d. Study entrance form.
- e. Radiation treatment summary. A daily schedule of pion therapy will be prepared at LAMPF. This report will also include an end of treatment examination to include weight, pertinent general physical examination, performance status, current medications, and, if possible, an assessment of tumor response.
- f. Follow-up examination form.
- g. Pathology form.

12.0 PATIENT CONSENT AND PEER JUDGMENT

All institutional, Food and Drug Administration, and National Cancer Institute regulations requiring submission to the institutional human experimentation committee and the use of procedures for obtaining and recording informed consent will be followed. A patient may be removed from the study if the study is not in the best interest of the patient. A patient may withdraw voluntarily from the study at any time, as will be indicated in the consent form.

13.0 REFERENCES

1. Kligerman, M., Bush, S., Kondo, M., Wilson, S., Smith A.R.: Results of Phase I/II trials of pion radiotherapy. In Proceedings of the Second Rome International Symposium on Biological Bases and Clinical Implications of Radioresistance, in press.
2. Kligerman, M.M., Hogstrom, K.R., Lane, R.B., Somers, J.: Prior immobilization and positioning for more efficient radiotherapy. Int J Radiat Oncol Biol Phys 2:1141-1144, 1977.
3. Hogstrom, K.R., Smith, A.R., Simon, S.L., Somers, J.W., Lane, R.G., Rosen, I.I., Kelsey, C.A., von Essen, C.F., Kligerman, M.M., Berardo, P.A., Zink, S.M.: Static pion beam treatment planning of deep seated tumors using computerized tomographic scans at LAMPF. Int J Radiat Oncol Biol Phys 5:875-886, 1979.
4. Tsujii, H., Bagshaw, M., Smith, A., von Essen, C., Mettler, F., Kligerman, M.: Localization of structures for pion radiotherapy by computerized tomography and orthodiagraphic projection. Int J Radiat Oncol Biol Phys 6:319-325, 1980.

APPENDIX I

KARNOFSKY PERFORMANCE STATUS

- 100 Normal; no complaints; no evidence of disease.
- 90 Able to carry on normal activity; minor signs or symptoms of disease.
- 80 Normal activity with effort; some sign or symptoms of disease.
- 70 Cares for self, unable to carry on normal activity or do active work.
- 60 Requires occasional assistance, but is able to care for most personal needs.
- 50 Requires considerable assistance and frequent medical care.
- 40 Disabled; requires special care and assistance.
- 30 Severely disabled; hospitalization is indicated, although death no imminent.
- 20 Very sick; hospitalization necessary; active support treatment is necessary.
- 10 Moribund; fatal process progressing rapidly.
- 0 Dead.

APPENDIX II

PATIENT CONSENT FORM FOR PI MESON RADIATION THERAPY FOR
METASTATIC CANCER*

Patient's Name: _____

Address: _____

Hospital/Clinic: _____

Hospital/Clinic I.D. Number: _____

1. I, _____, agree to take part in a
Name of Patient
research study of pi meson radiation treatment for cancer that has spread. The pi meson radiation treatment will be given at the Clinton P. Anderson Meson Physics Facility in Los Alamos, New Mexico. Dr. Steven E. Bush and doctors he has chosen will do this study. Persons helping them will be supervised by a doctor at all times while treatment is being given.
2. The treatment to be given to me has been described to me by Dr. _____. It is as follows:
 - a. If I choose to be in the study and the physical examination and tests show that I am able to be in the study, I must agree to spend the needed time in Los Alamos for treatment. I must also agree to return to the University of New Mexico Cancer Research and Treatment Center for any check-ups and tests needed after the pi meson radiation treatments.
 - b. I will be given pi meson radiation treatments, usually five days a week, for about eight weeks.
 - c. Before treatment, I will receive standard tests and examinations. These tests will include x-ray pictures and scans so that the persons treating me can see what area should be treated.
 - d. Before treatment, I will be placed in the exact position that I will be in during treatment. This set-up is done in a room near the treatment room. X-ray pictures will be taken to see if the treatment planned for me is correct.

*Sample Consent Form submitted by the Study Chairman.

- e. I will receive treatment in the same set-up position. There will be no pain or feeling from the pi meson beam during treatment. I will be alone in the treatment room, but persons treating me can see me on closed-circuit television. We will also be able to talk to each other through the microphone and speaker system. People will always be outside the treatment room and ready to help me.
- f. After the pi meson treatments end, I will receive standard medical tests to see what the treatments have done.
3. Dr. _____ has told me that I might not feel well after the pi meson radiation treatments. Complete information on problems and risks from pi meson treatment is not known. Tests with cells, animals, and patients have shown that pi meson radiation does not create problems much different from problems created by standard radiation treatments. Both pi meson and standard radiation could cause some or all of the following problems and risks: (Insert list for tumor site to be treated: _____). Attach signed list to consent form.
4. Dr. _____ has told me about the good things this research study might do for me and for other people.
- a. Pi meson treatment might make me feel better while I am being treated.
- b. Pi meson treatment might shrink the tumor better than other treatments and improve chances for control of my disease.
5. Dr. _____ has told me about other treatments for me.
- a. Drug treatments.
- b. Standard radiation.
- c. Surgery.
6. Dr. _____ will answer any question I have during the treatment.
7. I know that the treatment could harm me. No one has said that it wouldn't. I can stop having treatment at any time I want to.
8. Dr. _____ is in charge of my treatment. He can change the treatment at any time, or stop it.
9. If my body is injured by the research treatment, more than or different from that explained above, I understand that any emergency medical care I need will be given to me at no cost, but I will not be paid any money. Payment for medical costs will not continue after the emergency treatment is finished.

10. I understand that by signing this paper, I am not giving up my legal rights. State laws exist which may help people who think they have been treated carelessly. For information, I can write or call the Risk Management Division, Room 24, Lamy Building, Santa Fe, New Mexico 87503.

Date: _____ Time: _____ Date: _____

Signed: _____ Witness: _____

Parent or Guardian When Indicated _____
Witness: _____

cc: Patient

PELVIC AND ABDOMINAL LESIONS, MALE PATIENTS

Possible Problems and Risks

1. I may get ulcers and other sores in my stomach and small or large intestine. Doctors rarely see this happen with standard radiation treatment, and it is not likely with pi meson radiation treatment.
2. I may have changes in blood cells. Tests are given every week or more often for this. I will be treated right away.
3. I may lose hair in the area being treated.
4. My skin may get red and peel in the treatment area.
5. I may have weakness in some parts of my body and not be able to ~~more those parts~~. This problem does not happen very often in usual radiation treatments, so it is not expected to happen very often to patients receiving pi meson radiation.
6. I may have pain and swelling in the treatment area.
7. I may have diarrhea. Bleeding could happen with the diarrhea. I understand that these problems usually stop at the end of the treatment. I may be given medicine for these problems.
8. I may be sick at my stomach. This problem can be helped by medicine or by slowing the rate of radiation. Sometimes both methods are used to ease this problem.
9. I may have to pass my water more often. Sometimes I may have burning pain when I pass my water. These problems usually go away after the treatment is ended.
10. I understand that about 40% of men who are treated may not be able to produce children or have sex.

Signed: _____
Patient

Date: _____ Time: _____

PELVIC AND ABDOMINAL LESIONS, FEMALE PATIENTS

Possible Problems and Risks

1. I may get ulcers or other sores in my stomach and small or large intestine with pi meson radiation. Doctors rarely see this happen with usual radiation, so it is not likely to happen with pi meson radiation.
2. I may have changes in my blood cells. Tests will be done every week or more often for this. I will be treated right away.
3. I may lose my hair in the area being treated.
4. My skin may get red and peel in the treatment area.
5. I may have weakness in some parts of my body and not be able to move those parts. This problem does not happen very often in usual radiation treatment, so it is not expected to happen very often to patients receiving pi meson radiation.
6. I may have pain and swelling in the treatment area.
7. I may have diarrhea and some bleeding with the diarrhea. This problem can be treated quickly, and it usually goes away after the treatments are over.
8. I may be sick at my stomach. This problem can be helped by drugs or by slowing the rate of radiation. Sometimes both methods are used to ease this problem.
9. I may have to pass water more often. Sometimes I may have burning pain when I pass my water. These problems usually go away after the treatment is ended.
10. I understand that my monthly periods may stop, and I may not be able to have children.
11. I may have a discharge from the vagina.

Signed: _____
Patient

Date: _____ Time: _____

HEAD AND NECK LESIONS

Possible Problems and Risks

1. No matter what type of radiation I am given, I might need an operation after the radiation which might make me lose my voice forever.
2. I may have weakness in some parts of my body and not be able to move those parts. This problem does not happen very often.
3. I may have unusual openings in my skin or other tissue. These openings might heal themselves, or I might need surgery to repair them.
4. I may have pain and swelling in the treatment area.
5. I may lose normal bone or tissue in the treatment area.
6. I may get cavities in my teeth.
7. I may get ulcers in my mouth and throat. These ulcers might go away or be permanent.
8. I may have sore throat and trouble swallowing.
9. I might have a cough.
10. I might have trouble breathing.
11. I may have changes in blood cells. Tests are given every week or more often for this. I will be treated right away.
12. I may have a fever.
13. I may have more chance of getting an infection.
14. Later, I may get cancer of the thyroid, but this problem does not happen very often.
15. My skin may get red and peel in the treatment area.
16. I might have much wetness or dryness near the top of my breathing tubes or food tubes.
17. I might lose my sense of taste. This loss usually does not last long.
18. I might lose hair in the treatment area.
19. I might get cataracts (clouding of the lenses in my eyes). This is not expected, but if it does happen it can be corrected by an operation.

Signed: _____
Patient

Date: _____ Time: _____

CHEST LESIONS

Possible Problems and Risks

1. My lungs may become red and scarred. The redness may go away or leave scars. The scars usually cause no problems that would harm me. Long-term problems were found in one out of 133 patients in one series of studies with usual radiation. I may have trouble breathing.
2. I may have weakness in some parts of my body and not be able to move those parts. This problem does not happen very often.
3. I may have unusual openings in my skin or other tissues. These openings might heal themselves, or I might need surgery to repair them.
4. I may have pain and swelling in the treatment area.
5. I might lose normal bone or muscle tissue in the treatment area.
6. I may have a sore throat and trouble swallowing.
7. I might have a cough.
8. I might have trouble breathing.
9. I may have changes in blood cells. Tests are given every week or more often for this. I will be treated right away.
10. I may have a fever.
11. I may have more chance of getting an infection.
12. Later, I may get cancer of the thyroid, but this problem does not happen very often.
13. My skin may get red and peel in the treatment area. Later, I might get skin cancer.
14. I might have much wetness or dryness near the top of my breathing tubes or food tubes.
15. I might lose hair in the treatment area.

Signed: _____
Patient

Date: _____ Time: _____

BRAIN LESIONS

Possible Problems and Risks

1. Patients with brain cancer often have some problems that are there before treatment. Treatments can stir up these problems for a time. Such problems are:
 - a. I may be sick at my stomach. This problem can be helped by drugs or by slowing the rate of radiation. Sometimes both methods are used to ease the problem.
 - b. I may have headaches, but these can be treated with medicine.
 - c. I may be drowsy, but this can be treated with medicine.
 - d. I may have double vision.
2. I may not feel well after the treatments. Some of the problems that might be caused by the treatments are:
 - a. Parts of my normal brain tissue might be destroyed. This could cause weakness in some parts of my body, and I may not be able to move those parts. I might also have trouble seeing, hearing, smelling, touching or tasting. I might also have trouble in thinking.
 - b. My skin may get red and peel in the treatment area. Later, I might get skin cancer.
 - c. I will lose my hair, but it will probably grow back after treatment.
 - d. I might get cataracts (clouding of the lenses in my eyes). This is not expected, but if it does happen it can be corrected by an operation.

Signed: _____
Patient

Date: _____ Time: _____

WOMEN OF CHILD-BEARING AGE

Possible Problems and Risks

Women of child-bearing age should understand that the pion treatments, like x-rays or other radiation, could cause changes that might result in birth defects in children born after treatment has been given. The chance of this happening is not known. Women who plan to have children at any time after they complete treatment should seek counseling from doctors who are qualified to help them understand the extent of this risk.

Signed: _____
Patient

Date: _____ Time: _____

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