INDEX (10/2/08)

RADIATION THERAPY ONCOLOGY GROUP

RTOG 0630

A Phase II Trial of Image Guided Preoperative Radiotherapy for Primary Soft Tissue Sarcomas of the Extremity

SCHEMA

Preoperative IGRT **Postoperative Radiotherapy Boost**

_____(N) 15. Is there a lymph node or distant metastases?

_____(N) 16. Is there a recurrent tumor following previous potentially curative therapy?

1.0 INTRODUCTION

1.1

Basic fibroblast growth factor

radiotherapy.[69] The focus of their HRQOL inquiry was patient function and physical disability using the musculoskeletal tumor rating scale (MSTS) and the Toronto Extremity Salvage Score (TESS). Of the 129 patients available for analysis
scores in the HRQOL inquiry, 52 patients were less than age 50; neither mean age nor range was reported. They reported no rence in the scores of TESS and MSTS between preoperative versus postoperat
postop mean 81.3; p=0.17 for TESS, and preop mean 29.9 versus postop mean 28.0; p=0.08 for MTSS, respectively). However, patients who had ≥ grade 2 fibrosis, joint stiffness, and edema reported significantly physical disability as measured by the TESS (fibrosis 77.1 versus 87.0, p=0.001; joint stiffness 69.4 versus 86.4, p=0.001; edema 71.9 ve
amputation.

[71]

It is apparent that the data are variable regarding the impact of RT on functional status and QOL. In

their lives. The study sample of 100 was one year-post treatment; the majority of patients were male, with a mean age of 55 years. The stepw

2.2.3 To estimate the rates of local failure, local-regional failure, distant failure, distant-disease-free survival, disease-free survival, overall survival, and second primary tumor;

2.2.4 To estimate the rate of wound complications;

2.2.5 To correlate the degree of late radiation morbidity (defined as any ≥ grade 2 lymphedema, subcutaneous fibrosis, or joint sti

5.3 Pre-Registration Requirements for 3D-CRT Treatment Approach

5.3.1 Only institutions that have met the technology requirements and that have provided the baseline physics information that are described in 3D-CRT Quality Assurance Guidelines may enter patients to this study.

5.3.2

a screen that confirms that t

check that the registration software has functioned properly when a shift of patient position is carried out.

6.3 Localization, Simulation, and Immobilization

Patients should be immobilized in stable and comfortable positions to allow accurate repositioning from treatment to treatment and to prevent movement during treatments. A variety of immobilization devises may be utilized, including Alpha Cradle and thermoplastic casts. Radiotherapy treatment plans will be generated after limb immobilization and computerized tomography (CT) simulation.

Adjustments of patient position should be made accordingly, if needed prior to treatment. Pretreatment images may include 2 or 3D imaging acquired using the techniques described in Section 6.2.2. The number of prrehesenede Fac4ris d number d in

oncologist. Full prescription dose to skin over

6.9 Radiation Therapy Adverse Events (4/20/09)

AdEERS. All RTOG case report forms will continue to use CTCAE, v. 3.0. A copy of the CTCAE v. 4 can be downloaded from the CTEP home page (http://ctep.cancer.gov) or the RTOG web site (http://www.rtog.org/members/toxicity/main.html). All appropriate treatment areas should have access to a copy of the CTCAE v. 4.

- “24 hours” calendar time. The investigator must initially report the AE via AdEERS within 24 hours

-0.0001 Tc-0

-0.0003 Tc-0

)http://www.rtog.org/members/toxicity/main.html site (
).. All appropriate treatment areas should have access to Adverse Ev

that meet the criteria defined above
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Although every effort should be made to perform limb preservation surgery, some extremity tumors may require amputation to obtain negative margins if a limb preservation approach is not possible after preoperative radiation. In this scenario, amputation would still be considered adequate surgical therapy and margin status will be assessed or categorized based upon the R criteria for limb sparing surgery.

9.0 OTHER THERAPY

A number of biomarkers are under investigation by the RTOG Sarcoma TRP group. The results of these ongoing studies will lead to the investigation of promising similar or new biomarkers with the goals of 1) identifying factors predictive of outcome such that patients may be better stratified in future trials, and 2) developing novel treatment strategies which target the molecular

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- Á Unacceptable adverse events [at the discretion of the treating physician(s)];
- Á A delay in protocol treatment > 12 weeks.

If protocol treatment is discontinued, follow up and data collection will continue as specified in the protocol.

11.7 Musculoskeletal Tumor Rating Scale

[72] is a measure of physical function across 7 items, completed by the physician (preferably by the Orthopedic Surgeon or Surgical Oncologist) or the physicianBs designated staff. The 7 items are: pain, range of motion, strength, joint stability, joint deformity, emotional acceptance, and overall function. Each item is scored from 0-5 with a maximum possible score of

12.1 Summary of Data Submission

Item	Due

13.0 STATISTICAL CONSIDERATIONS

13.1 Study Endpoints

cohort, except as noted in Section (134.3.( )Tj/TT6 1 Tf-64.7650 -1.4377 TD-0.0063 Tc143532 Tw[(13.3.1Primardy)16.6

radiation

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APPENDIX I

RTOG 0630

Informed Consent Template for Cancer Treatment Trials
(English Language)

Required Submission of Tumor Tissue
Your study doctor will need to send some of the tumor tissue obtained at the time of your biopsy or surgery to a central office. There, a pathologist will confirm your type of tumor. This tissue submission for review is required for this study.

Group A (receiving chem8therapy) **[Closed 1/8/10]**
You will receive radiation as an outpatient, once a day, Monday through Friday, for about 22-25 days. Each radiation treatment takes up to 30 minutes. Your doctor will discuss the type, dose, and timing of chem8therapy (before or during radiation or after surgery) you receive.

Group B
You will receive radiation as an outpatient, o a aday, Monday through Friday, for about 25 days. Each radiation treatment takes up to 30 minutes.

Radiation After Surgery
Patients with tumor cells at the edges of the tissue remov
alaurg, dos ind1n treatmeny)tor will receive radiation

You will need these tests and procedures in follow-up visits: (1/8/10)
They are being done to see how you and your cancer was affected by the treatment you received.

Every 3 months in years 1-2 and every 6 months in years 3-5, then once a year:

- Physical examination
- Evaluation of your ability to carry out daily activities
- Evaluation of any side effects from treatment you may be having

Every 6 months in years 1-2 and once a year in years 3-5, then once a year:

How long will I be in the study? (1/8/10)

All patients will receive radiation treatment for about 25 days, and all patients will have surgery 4-8 weeks after radiation treatment is completed.

Patients with tumor cells at the edges of the tissue removed in surgery will receive radiation either during surgery or after surgery. You can discuss the length of time of this radiation with your doctor.

Patients will be seen for follow-up visits at least every 3 months for years 1 and 2, although it may be more frequent, if your doctor recommends it. Then follow-up visits will take place every 6 months during years 3

the skin in the treated area may turn red, blister, and/or peel. In general, most radiation reactions (other than fatigue) are limited to the site being treated. For example, if your leg is being treated, you will not feel naus (on5rE2 Twa65rh

Less Likely

- Treatment of large tumors with radiation and surgery may result in infection or lack of healing, which could lead to a longer time in the hospital and rarely, to surgically removing the arm or leg.

Risks and side effects related to Blood Draws

Risks seen with taking blood from a vein in your arm include pain, bruising, lightheadedness, fainting, and, on rare occasions, infection.

Reproductive risks (1/8/10)

You should not become pregnant or father a baby while on th6s study because the radiation treatment in this study can affect an unborn baby. Women who can have children are required to have a pregnancy test before treatment on this study. Women should not breastfeed a baby

What are the costs of taking part in this study?

You and/or your health plan/ insurance company will need to pay for some or all of the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

You will not be paid for taking part in this study.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

What happens if I am injured because I took part in this study?

It is important that you [investigator(s)], if you feel that you
ing part in this study. You

Please note: This section of the informed consent form is about additional research that is being done with people who are taking part in the main study. You may take part in this additional research if you want to. You can still be a part of the main study even if you say 'no' to taking part in this additional research.

You can say "yes" or "no" to each of the following studies. Below, please mark your choice for each study.

Quality of Life Study

We want to know your view of how your life has been affected by cancer and its treatment. This "Quality of Life" study looks at how you are feeling physically and emotionally during your cancer treatment. It also looks at how you are able to carry out your day-to-day activities.

This information will help doctors better understand how patients feel during treatments and what effects the medicines are having. In the future, this informati domay help patients and doctors as they decide which medicines to use to treat cancer.

You will be asked to complete 3 questionnaires at the following times: before starting protocol treatment and at 12, 18, and 24 months from the start of treatment. It takes about 10-15 minutes to fill out each questionnaire.

If any questionsomake you feel uncomfortable, you may skip those questionsoand not give an answer.

If you decide to take part in this study, the only thing you will be asked to do is fill out the questionnaires. You may change your mind about completing the questionnaires at any time.

Just like in the main study, we will do our best to make sureatmen3892 0 TD0.0001 Tc(re that your personal inform)Tj12.2275

3. Someone may contact me in the future to ask me to take part in more research.

1-800-4-CANCER (1-800-422-6237) or **TTY: 1-800-332-8615**

You may also visit the NCI We/ Pce a

APPENDIX III (4/20/09)

ZUBROD PERFORMANCE SCALE

0	**Fully active, able to carry on all pre-disease activities without restriction**
1	**Restricted in physically strenuous activity but ambulatory and able to carry work of a light or sedentary nature. For example, light housework, office of .-6 Tc-0.033 Tw[(wo)30.7(r)30.5(k)29.9( )]TJ/TT2 1 Tf0 -1.1138 TD0 Tc0 Tw( )Tj/TT6 1 T**

APPENDIX IV

Staging System for Soft Tissue Sarcomas

APPENDIX VII (10/2/08, 10/13/09)
RTOG Blood Collection Kit and Instructions

Instructions for use of serum, plasma, or buffy coat collection kit