(3 1 0) 7 9 2 2 4 . 0 7

hADIATION THERAPY ONCOLOGY GROUP

UCLA Medicl RCenter20 UCLA Medicl RPlaza, Suite B265L o s A n g

hTOG 0438

A PHASE I TRIAL OF HIGHLY CONFORMAL hADIATION THERAPY FOR PATIENTS WITH LIVER METASTASES

Translational Research Co-Chair

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RADIATION THERAPY ONCOLOGY GROUP

RTOG 0438

SCHEMA

RTOG Institution # _____

RTOG 0438 **ELIGIBILITY CHECKLIST (11/3/05) (11/3/05)**

Case #

RTOG Institution # ___

RTOG 0438 **ELIGIBILITY CHECKLIST (11/3/05)**

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_____ Has the patient had unstable angina and/or CHF requiring hospitalization within the last 6 months?

_____ Has the patient had a transmural MI within the last 6 months?

_____ Has the patient had an acute bacterial or fungal infection requiring antibiotics at the time of registration?

_____ Has the patient had a COPD exacerbation or other respiratory illness requiring hospitalization or precluding study therapy at the time of registration?

_____ Does the patient have active hepatitis or clinically significant liver failure?

_____ Is the patient currently receiving anticoagulation treatment with coumadin or IV heparin?

_____ Is there CNS metastasis?

_____ Is there liver cirrhosis?

_____ Is there clinical ascites?

_____ Is the patient, male or female, of reproductive potential?

_____ Will a medically acceptable form of contraception be used?

- Absolute neutrophil count (ANC) ≥

5.1.1 Each institution must complete the 3D QA Facility Questionnaire for Stereotactic Body Radiation Therapy (SBRT) available on the ATC web site, http://atc.wustl.edu. Each institution must submit the completed Facility Questionnaire by email, fax, or mail to:

Image-Guided Therapy Center (ITC)
Attn: Roxana Haynes
4511 Forest Park Avenue, Suite 200
St. Louis, MO 63108
E-mail:

6.1.5 Table of permitted doses (in Gy)

Level	Total Dose (Gy)	Dose/fraction (100%)	PTV dose	
			Maximum (120%)	Minimum (90%)

6.4.6 All volumes delineated on the CT and the entire plan should be sent for QA. Digital data transfer of the plan, including target GTV, CTV and PTVs, normal tissue volumes, the 3D dose distribution and DVHs of all structures defined, is required.

1. Beam verification imaging or films are required prdc-to every radiation fraction. A minimum of one pair of angled verification images or film must be acquired to confirm the position of at least one isocenter. CT scans (e.g. cone beam, tomotherapy, etc.) obtained in the treatment room are recommended if possible. If not, then verification of the treatment isocenter can be performed by one of the following methods. For a conventional linear accelerator, standard port film or portal imaging verification techniques are acceptable (preferably demonstrating soft tissue, e.g., diaphragm)
2. For the BrainLAB Novalis units with first generatJ11aging 1ag51 Tw[(ent room are recomm40.1

6.5.2 Kidney: For patients with only one functioning kidney or creatinine > 2.0 mg/dl, no more than 10% of the functioning kidney(s) ma y receive 10 Gy or more. For patients with normal creatinine and two functioning kidneys, no more than 33% of the combined

6.9.3 Thrombocytopenia: Transient thrombocytopenia may occur following radiation. If the platelets drop to 50,000cells/mm^3 during radiation, radiat

RTOG REPORTING REQUIREMENTS

AdEERS provides a radiation therapy (RT)-onl

9.0 OTHER THERAPY

9.1 Permitted Supportive Therapy

All supportive therapy for optimal medical care will be given during the study period at the discretion of the attending physician(s) within the parameters of the protocol and documented on each site's source documents as concomitant medication.

9.1.2 Treatment for RILD with repeat paracenteses, diuretics (Spironolactone), and close follow-up is recommended.

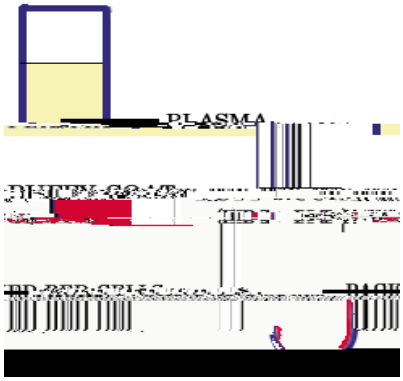
9.1.3 H2 blockers or proton pump inhibitors are required. See Section 6.9.2

9.2 Non-Permitted Supportive Therapy (8/7/07)

9.2.1 Coumadin and IV heparin are not allowed.

9.2.2 No chemotherapy and/or targeted agents within 2 weeks prior to start of RT, during RT,

For a visual explanation of Buffy coat, please refer to diagram below:



and placed in an airtight plastic biohazard bag (i.e., resealable bag). Serum, plasma, or buffy coat specimens requiring specific infectious precautions should be indicated clearly, with the specific source of infectious concern listed, if known. Place the biohazard bag into the Styrofoam shipping container and fill the container with a generous amount of dry ice and place the Styrofoam lid. All pertinent paperwork as described in Sections 10.2.1 and 10.2.2 should be placed on top of the Styrofoam container, but within the cardboard shipping box. Seal the outer cardboard container with plastic tapetyrtyr Specimens should be sent only Monday through Wednesday due to shipping, delivery and time required for processing. Saturday deliveries will not be acceptedtyrBe cautious to avoid shipping close to holidays as welltyr

r

Blood Samples that are received thawed or unfrozen will be discarded and a notification will be sent immef

R T O G 0 4

treatment at Dose Level I, if there are 0 or

REFERENCES

1. Landis SH, Murray T, Bolden S, Wingo PA. Cancer statistics, 1998. *CA Cancer J Clin.* 1998;48:6-29.

2. Weiss L, Grundmann E, Torhorst J, et al. Haematogenous metastatic patterns in colonic carcinoma: an

APPENDIX I

RTOG 0438

Informed Consent for Cancer Treatment Trial

What other choices do I have if I do not take part in this study?

Your other choices may include:

- ∉ Getting radiation treatment or care for your cancer without being in a study
- ∉ Chemotherapy
- ∉ Other treatments to eliminate the tumor by applying cold (cryotherapy) or heat (radiofrequency ablation).
- ∉ Taking part in another study
- ∉ Getting no treatment

What are my rights if I take part in this study?

CONSENT FOR USE OF BLOOD FOR RESEARCH

samples – see above instructions).

4. Remove the buffy coat cells carefully and place into the 1ml cryovials labeled “buffy coat” (*it is okay if a few packed red cells are inadvertently collected in the process*). Clearly mark the tubes with date and