RTOG 0438, A Phase I Trial of Highly Conformal Radiation Therapy for Patients With Liver Metastases

Study Chair: Alan W. Katz, MD, MPH; (585) 275-3913; Alan_Katz@urmc.rochester.edu

RTOG 0438 has been amended as follows:

As mandated by CTEP, this study will utilize CTCAE version 4.0 for AdEERS reporting of adverse events beginning April 1, 2011. Related changes were made to Section 6.10. (AdEERS Reporting Requirements and RTOG Reporting Requirements). All AE reporting on the study case report forms will continue to use CTCAE version 3.0.

Note: References to CTCAE, version 3.0, may remain in the protocol. These are appropriate, as treatment decision for patients enrolled on this study were based on that version.

Other Changes:
Cover Page: A document version history was added to the Cover Page per current RTOG standard.

Section 6.10.2: Text referring to AML/MDS paper report forms has been removed since AdEERS will now be used for reporting AML or MDS and additional notification to CTEP is no longer required. Instructions for submitting a hard copy of the report, including the RTOG HQ address, have also been deleted per current RTOG standard.
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RTOG 0438 has been updated as follows:

Eligibility Checklist, page 2, element 14: This question was amended in error during Amendment 2. The timeframe had been erroneously changed from 30 days to 6 weeks and was therefore updated to revert to the original timeframe (30 days).
SUMMARY OF CHANGES
Amendment 2, Version Date: August 7, 2007

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Study Chair: Alan W. Katz, MD, MPH; (585) 275-3913; Alan_Katz@urmc.rochester.edu

RTOG 0438 has been amended as follows:

Cover Page: The phone number for Dr. Katz was updated.

Section 3.1.2: The time interval from imaging study to registration was increased from 30 days to 6 weeks. As the tumor will be defined on planning CT studies, this increase in time from diagnostic scans to planning is not anticipated to adversely alter outcome. Mandating repeat diagnostic scans too early can lead to a delay in treatment and possibly lead to tumor growth. The corresponding Eligibility Checklist question was updated.

Section 3.1.3: The maximal dimension of liver metastasis was increased from 6 to 8 cm, because patients with these tumors are not eligible for other ablative therapies and there is now safety and efficacy data on using radiation therapy for these patients.

Section 3.1.11: The time interval from therapy completion to radiation was decreased from 4 to 2 weeks because it is not anticipated to adversely alter toxicity; targeted therapy was added for increased clarity. The corresponding Eligibility Checklist questions were updated, as was Section 9.2.2.

Sections 3.2.2, 3.2.3, and 3.2.5: Deleted because these stipulations are already accounted for via the eligibility criteria (Section 3.1). All affected sections were appropriately renumbered.

Section 5.1.2: FTP was changed to SFTP because the account is now secured. This change was also made to Section 12.1.1, first paragraph, third sentence.

Section 6.1.3, third sentence: "Except for adjacent tumors, in which the maximum dose outside the PTV must be < 115%" was added parenthetically, so that multiple tumors can be treated without under-dosing the tumors.

Section 6.1.4: "Maximum doses described in Section 6.1.3 are defined at 1 cc of volume. Minimum dose to the PTV is defined as minimum dose to 99.0% of the PTV" added as the new Section 6.1.4 for clarification and consistency with ATC. The point minimum and maximum doses are flawed given the resolution of ROI definition and dose grid. All subsequent sections were appropriately renumbered.
Section 6.3.2: In the last sentence "breath or gating" was changed to "immobilization" for increased clarity.

Section 6.3.4: Rewritten because not all tumors move less than 5 mm. This approach of measuring motion on respiratory-sorted CT allows motion to be measured and considered to help in PTV definition for that patient.

Section 6.4.4, last sentence: The maximal PTV was increased from 10 to 30 mm and "dependent on the immobilization method used and breathing method" was added, because many patients cannot have tumor motion reduced to a 5-mm limit. There are safety data available on treating tumors that move more with appropriate PTV increase as long as the normal tissue dose constraints are met.

Contact information for LDS was updated in the following places:

- Section 10.2.4, first paragraph, last sentence
- Section 10.2.5

Section 12.1.1, second paragraph: The zip code for ITC was corrected.
SUMMARY OF CHANGES
Amendment #1, Version Date: April 21, 2006

RTOG 0438, "A Phase I Trial of Highly Conformal Radiation Therapy for Patients with Liver Metastases"

Study Chair: Alan W. Katz, MD, M.P.H., Phone (585) 273-5618; email: Alan_Katz@urmc.rochester.edu

RTOG 0438 has been amended as follows:

Eligibility Checklist - page 2 of 3:

- The question: "If there is disease outside the liver, is the liver disease judged to be life-limiting?" was added to the top of the page for consistency with the eligibility criteria.
- Third question from bottom was amended to: "Has the patient had a prior invasive malignancy, other than liver metastasis primary?" to avoid ambiguity.

Section 3.1.4: "Extrahepatic disease outside the liver is permitted if the hepatic disease is judged to be life-limiting" was added to the eligibility criteria to avoid ambiguity. As a result of this addition, all subsequent sections have been renumbered.

Section 3.2.1: "other than liver metastasis primary" was added to the sentence to avoid ambiguity.

Section 6.9: The heading of the section changed from "Radiation Toxicity" to "Radiation Adverse Events" to correspond with the NCI's updated AE reporting guidelines.

Sections 6.10: The Radiation Adverse Event Reporting section was amended per the NCI's updated AE reporting guidelines.

Section 10.2:

- Under Section 10.2.3: "Blood Collection", the procedure for collecting blood and serum for banking was updated per RTOG's blood/serum/tissue banking facility, LDS Hospital in Utah.
- Under Section 10.2.4: Packaging and shipping procedures for specimen vials were updated per RTOG's blood/serum/tissue banking facility, LDS Hospital in Utah.
- Under Section 10.2.5: The contact information for LDS Hospital was updated.

Section 10.3: Reimbursement amounts were updated for specimen collection.

Appendix III: The procedure for collecting blood and serum for banking was updated per RTOG's blood/serum/tissue banking facility, LDS Hospital in Utah.
An updated protocol is available (no password required) on the RTOG Web site, www.rtog.org
SUMMARY OF CHANGES  
Update Date: January 10, 2006

RTOG 0438, "A Phase I Trial of Highly Conformal Radiation Therapy for Patients with Liver Metastases"

Study Chair: Alan W. Katz, MD, M.P.H., Phone (585) 273-5618; email: Alan_Katz@urmc.rochester.edu

RTOG 0438 was updated as follows:

Cover Page: Co-Chair, Dr Laura Dawson's contact information was updated.

Section 6.0: The sentence, "Radiation Therapy must start within 4 weeks of patient registration" was added for clarity.

Section 12.2: In the Summary of Data Submission table, the typo, "third 3year" was corrected to "third year".

Informed Consent:

- Under "How many people will take part in the study?" the typo, "33 people" was corrected as, "18 people" per the study's required sample size.
- Under "How long will I be in the study?" the sentence, "at least 3 years" replaced, "at least 5 years" for consistency.

NOTE: This is an editorial/administrative change to the Protocol. NCI now requires that these changes be documented on the Protocol title page with the date of the updated noted as "Update Date", not as a revision.

An updated protocol is available (no password required) on the RTOG Web site, www.rtog.org
SUMMARY OF CHANGES
Update Date: November 3, 2005

RTOG 0438, "A Phase I Trial of Highly Conformal Radiation Therapy for Patients with Liver Metastases"

Study Chair: Alan W. Katz, MD, M.P.H., Phone (585) 273-5618; email: Alan_Katz@urmc.rochester.edu

RTOG 0438 has been updated as follows:
Eligibility Checklist:

- "On-Line" replaced "Study" in the header: "The following questions will be asked at On-Line Registration:
- "Has the eligibility checklist been completed?" was added for clarity.
- "Is the patient eligible for this study?" was added for clarity.
- "Is there liver cirrhosis?" was added for clarity.
- "Is there clinical ascites?" was added for clarity.
- "Is the patient, male or female, of reproductive potential?" was added for clarity.
- "Will a medically acceptable form of contraception be used?" was changed from "Is a medically acceptable form of contraception being used? (if applicable)" for clarity.

Section 12.1.3: "DDSI" has replaced the code "T2" for the Digital Data Submission Form, per ITC.

NOTE: This is an editorial/administrative change to the Protocol. NCI now requires that these changes be documented on the Protocol title page with the date of the updated noted as "Update Date", not as a revision.

An updated protocol is available (no password required) on the RTOG Web site, http://www.rtog.org