

North Central Cancer Treatment Group

N0275: Phase II Trial Evaluating Resection followed by Adjuvant Radiation Therapy (RT) for Patients with Desmoplastic Melanoma

Addendum 1 – April 9, 2004

Summary

Scientific:

Scientific changes have been made to the protocol due to greater clinical experience gained in the months since writing the study. These changes are designed to clarify the doses and increase safety. Frequently, all the radiation oncologist has to work with is an operative report, pathology report, and patient with an incision. These parameters will be clearer and prevent misunderstanding in dose prescription. The margins are now designated from the incisions.

Editorial:

1. The position of NCCTG radiation study chair is now pending.
2. Correction to fax number of contact person for questions related to eligibility/treatment.
3. Editorial correction to the NCCTG nurse contact.

Replacement pages are included. Please incorporate into the protocol and keep this update with your protocol.

- Title page:
- The title page now reflects NCCTG Addendum 1.
 - The NCI Version Date is now March 18, 2004.
 - The position of NCCTG radiation study chair previously held by Randy L. Moore, D.O., is now pending until a replacement is found.
- Page 2:
- Correction to fax number of contact person for Butch Kvittem (contact person for questions related to eligibility/treatment:

Butch Kvittem
Phone: 507/284-3559
Fax: ~~507/284-1902~~ 507/266-7240
E-mail: kvittem@mayo.edu
 - Correction to the name of the NCCTG nurse contact:

~~Barbara~~ Anne Forsman, R.N.

Pages 9-19: Section 7.0 has been changed as follows:

7.0 Protocol Treatment

7.1 ~~RT must begin \leq 8 weeks of surgical excision. Patients will receive a total of 30 Gy in equal 5 fractions of 6 Gy, administered twice a week (Monday and Thursday or Tuesday and Friday) over approximately 2.5 weeks. Treatment will be administered with x rays or electrons. If the tumor is located in the head or neck region and its depth was \leq 4 mm depth, then 2 cm margins between the estimated tumor bed and the block edges will be used. If the tumor is located in the head or neck region and its depth was greater than 4 mm, then 3 cm margins between the estimated tumor bed and the block edges will be used. If the tumor is in a non head and neck region, then 5 cm margins between the estimated tumor bed and the block edges will be used. This will likely be best accomplished with electron therapy. Therefore, electron therapy is the preferred technique and x ray therapy (photons) should only be used if electrons cannot be used. The electron energy can be altered to treat to specific depths. If x rays are used, a minimum of 2 fields is to be used. The estimated tumor bed should receive at least 95% of the prescribed dose. A point at the center of the field and 2 cm below the tumor bed should receive at least 80% of the prescribed dose. Bolus should be used as necessary to achieve a surface dose of at least 90% of the prescribed dose. Bolus can also be used to decrease the penetration of a high-energy beam. None of the lung, spinal cord, eye, or brain can receive \geq 24 Gy.~~

~~7.2 Radiotherapy will not be given to the first echelon lymph nodes unless necessary to give adequate therapy to the primary tumor bed.~~

~~7.21 Radiation therapy will not be given to the lymph node basin even if the lymph nodes are positive.~~

Pages 9-19:

(continued)

7.1 RT must begin within 8 weeks of surgical excision. Healing should be adequate to begin RT safely. Patients will receive a total of 30 Gy in 5 fractions of 6 Gy prescribed to Dmax, administered twice-a-week (Monday and Thursday or Tuesday and Friday) over approximately 2.5 weeks. Treatment will be administered with electrons only. If the tumor is located in the head or neck region and its depth was ≤ 4 mm depth, then 2 cm margins between the estimated tumor bed (incision) and the block edges will be used. If the tumor is located in the head or neck region and its depth was greater than 4 mm, then 3 cm margins between the estimated tumor bed (incision) and the block edges will be used. If the tumor is in a non-head and neck region, then 3 cm margins between the estimated tumor bed (incision) and the block edges will be used. The incision is to be demarcated with a radio-opaque marker at the time of simulation. Simulation films should be taken. Radiotherapy will be accomplished with electrons. The electron energy can be altered to treat to specific depths. A point at the center of the incision at a depth equal to the thickness of the tumor on the pathology report should receive at least 90% of the prescribed (Dmax) dose. Additionally for thinner tumors, a point at the center of the field and 1.5 cm below the incision should receive at least 80% of the prescribed dose. Bolus should be used as necessary to achieve a surface dose of at least 90% of the prescribed dose. Bolus can also be used to decrease the penetration of a high-energy beam. None of the lung, spinal cord, eye, or brain (dose-limiting structures) can receive ≥ 24 Gy (this requirement is absolute and may lead to compromises in other treatment parameters in unusual circumstances). CT-derived treatment planning is to be performed when the field includes one of these dose-limiting structures. The CT should be performed with a radio-opaque marker on the incision. In situations with a dose-limiting structure within the field, isodose plans should be performed at 1 cm increments throughout the field length with the dose-limiting structure denoted on the isodoses plan. See Appendix II for other treatment planning reporting requirements. Central axis contours with isodoses shown are to be performed in all patients and is satisfactory alone in those with no dose-limiting structure in the field. The 95% (28.5 Gy), 90% (27 Gy), and 80% (24 Gy) isodoses are to be shown.

Pages 9-19: (continued)

7.2 Radiotherapy will not be given to the first echelon lymph nodes unless necessary to give adequate therapy to the primary tumor bed.

7.21 Radiation therapy will not be given to the lymph node basin even if the lymph nodes are positive.

Due to repagination on pages 11-19, there are now 20-numbered pages.

Appendix II: This appendix has been changed as follows:

1. Tumor bed Coverage (protocols requires a 2-5 **3** cm radiographic margin on **the simulation films from the incision**). **Simulation and CT should be performed with a radio-opaque marker on the incision.**
 - a. No deviation—coverage +/- 1 cm of specified.
 - b. Minor deviation--coverage +/- >1 to 2 cm of specified.
 - c. Major deviation-->2 cm of specified.
2. Regarding spinal cord/eye/lung/brain ~~Overdosage~~ **(dose-limiting structures) limits: ≤24 Gy**
 - ~~a.~~ No deviation--~~spinal cord dose~~ **dose-limiting structure: <105% of specified (max specified dose 24 Gy).**
 - b. Minor deviation--~~spinal cord dose~~ **dose-limiting structure: 106-110% of specified.**
 - c. Major deviation--~~spinal cord dose~~ **dose-limiting structure: >110% of specified.**
3. Isodoses--point dose calculations are not satisfactory. Composite isodose plots are required at central **axis** and ~~any~~ **all** dose-limiting structures must be shown on the isodose plot. This ~~may~~ **will** require CT-based dosimetry for fields ~~near these structures~~ **that include any of the above-mentioned, dose-limiting structures, at 1 cm intervals throughout the field length. For tumor sites distant from dose-limiting structures, a central axis composite isodoses plan will suffice. A radio-opaque marker should be placed on the incision for the CT and shown on the dosimetry plan.** The 95% (**28.5 Gy**), 90% (**27 Gy**), and 80% (**24 Gy**) isodoses must be shown on the plan. The depth of the tumor bed (**tumor thickness**) should be shown on the isodose plots. Simulation films (**with radio-opaque marker on the incision**) are required for submission.