

NORTH CENTRAL CANCER TREATMENT GROUP

Eligibility Checklist

07/25/2008
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**N0275: Phase II Trial Evaluating Resection followed by Adjuvant Radiation Therapy (RT) for Patients with
Desmoplastic Melanoma**

**To register a patient, access the NCCTG web page at <https://ncctg.mayo.edu/training> and
enter the remote registration/randomization application.**

Has the patient ever been on a prior study entered through this Registration Office? Yes No

If yes: Last protocol number _____; previous patient ID number _____

Registration date (date on) (mm/dd/yyyy) ___/___/_____

Patient study ID number (provided at time of Registration) _____

NCCTG member (participant sponsor) _____

NCCTG treating location (RT) _____

NCCTG treating physician (RT) _____

Institution patient number (local subject number) _____

IRB approval date (RT) (mm/dd/yyyy) ___/___/_____

Patient initials (last, first, middle) _____
(For Mayo Rochester patients, include first four letters of last name.)

Gender (check one) Male Female Unknown

Date of birth (mm/dd/yyyy) ___/___/_____

Zip code _____

Country of Residence _____

Method of payment (check one)

- PI (Private Insurance)
- MR (Medicare)
- MRP (Medicare and Private Insurance)
- MD (Medicaid)
- MM (Medicaid and Medicare)
- MVA (Military or Veterans Sponsored,
Not Otherwise Specified (NOS))
- MS (Military Sponsored [including CHAMPUS & TRCARE])
- MV (Veterans Sponsored)
- SP (Self pay [no insurance])
- NP (No means of payment [no insurance])
- OTH (Other)
- UNK (Unknown)

Race (check all that apply)

- White
- Black or African American
- Native Hawaiian or Other Pacific Islander
- Asian
- American Indian or Alaska Native
- Not reported: Patient refused or not available
- Unknown: Patient unsure

Ethnicity (check one)

- Not Hispanic or Latino
- Hispanic or Latino
- Not reported: Refused or data not available
- Unknown: Unsure of their ethnicity

Study reg. number _____

Eligibility Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be M/D/Y.

Yes No

- ____ ____ ≥18 years. Age = _____.
- ____ ____ ECOG performance status (PS) 0, 1, or 2. PS = _____.
- ____ ____ Pathologically proven DM ≥1 mm in depth or locally recurrent DM. Recurrent tumor is defined as a tumor found ≤2 cm from the previous excision or within the surgical bed (which includes the extent of previous skin flaps).
- ____ ____ DM resected with pathologically negative margins. Acceptable surgery includes standard wide local excision and Moh's surgery.
- Tumors on the trunk proximal extremities need to have a ≥2 cm negative margin. Tumors located on the head and neck and distal extremities will have an attempt at 2 cm negative margins but due to location and subsequent concern regarding cosmesis a margin <2 cm will be acceptable if margin is negative.
 - Margins from tumors resected using the Moh's techniques will be accepted if negative and best approximation of tumor with will be made.
- ____ ____ RT is to begin ≤8 weeks after definitive surgical resection. This will allow for definitive healing from the wide local excision. Due to the nature of the disease, there is the potential need for skin grafts and skin flaps to cover wounds which can be prone to wound healing issues. 8 weeks should allow adequate time for healing prior to radiation therapy.
- ____ ____ Adjuvant systemic therapy (immunotherapy or chemotherapy) must be postponed until irradiation is completed.

The utility of adjuvant systemic therapy is unknown for patients with desmoplastic melanoma. There is a benefit for patients with cutaneous melanoma who have stage III disease but due to the fact the subset of DM is so small it is impossible to evaluate that group. There are reports of increased in field toxicity in patients who receive adjuvant interferon therapy. Severe subacute and late complications were seen in 5 out of 10 patients who received concurrent or sequential alpha-interferon therapy. The decision to treat these patients will be left up to the treating physician.

All responses in above section must be "Yes."

- ____ ____ Previous irradiation to the same site.
- ____ ____ Non-healing surgical wound.
- ____ ____ Active infection at the surgical site.
- ____ ____ Evidence of metastatic disease. Local nodal disease is still eligible for the trial.
- ____ ____ Life expectancy <1 year.
- ____ ____ Melanoma with focally desmoplastic features, in which the desmoplastic melanoma is not the predominant histologic pattern of the tumor, will be excluded. Non-desmoplastic neurotropic melanoma and non-desmoplastic spindle cell melanoma are also excluded.
- ____ ____ Previous malignancy <5 years excluding basal cell carcinoma or squamous cell carcinoma of the skin or cervical carcinoma in situ (with the exception of patients who have stage I breast cancer who were adequately treated with adjuvant therapy and are currently disease free, and patients with stage I or II prostate cancer treated with prostatectomy or radiotherapy and are biochemically free of disease [for RRP PSA <0.3 and for radiotherapy PSA <2.0 above the post treatment nadir]).
- ____ ____ Any of the following:
- Pregnant women
 - Women of childbearing potential who are unwilling to employ adequate contraception (condoms, diaphragm, birth control pills, injections, intrauterine device [IUD], surgical sterilization, abstinence, etc.)

All responses in above section must be "No."

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Study reg. number _____

Registration Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be M/D/Y.

Yes No

- ____ Consent form signed and dated. Date of consent ____ - ____ - ____.
- ____ Authorization for use and disclosure of protected health information signed and dated.
- ____ Date of authorization ____ - ____ - ____ vs. Not applicable (Non-U.S.A. institution only) ____.
- ____ Treatment on this protocol must commence at the accruing membership under the supervision of a NCCTG member physician.
- ____ Treatment cannot begin prior to registration and must begin ≤ 30 days after registration.
- ____ Pretreatment tests must be completed within the guidelines specified on the test schedule (see Section 4.0).
 - Urine pregnancy test must be done ≤ 7 days prior to registration (see Section 4.0).
 - Urine pregnancy test date ____ - ____ - ____ vs. not done ____.
 - If urine pregnancy test not done, reason: _____.
- ____ All required baseline symptoms must be documented and graded on the on-study form.
- ____ A radiation oncologist has seen the patient and confirms the patient is a suitable candidate for this study.

All responses in above section must be "Yes."

Grouping Factor

- Desmoplastic melanoma type
- ____ ≥ 1 mm deep
- ____ Locally recurrent

Assigned Treatment

____ A) Radiotherapy

Person registering _____ Random. specialist _____
Signature initials

Physician _____ M - D - Y
Signature