

NORTH CENTRAL CANCER TREATMENT GROUP
Eligibility Checklist

10/09/2009
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N0321: **Phase I/II Study of PS-341 in Combination with Paclitaxel, Carboplatin, and Concurrent Thoracic Radiation Therapy for Non-small Cell Lung Cancer (NSCLC)**

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

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

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

NCCTG member (participant sponsor) _____

NCCTG treating location (chemo) _____

(RT) _____

NCCTG treating physician (chemo) _____

(RT) _____

Institution patient number (local subject number) _____

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

Patient initials (last, first, middle) _____

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

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

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

Yes No

Required Characteristics:

- ____ ____ ≥18 years of age. Age = _____.
- ____ ____ Histologic or cytologic confirmation of non-small cell lung carcinoma.
- ____ ____ Non-metastatic NSCLC requiring definitive radiation therapy.
- ____ ____ ECOG performance score (PS) 0 or 1. PS = _____.
- ____ ____ Life expectancy ≥12 weeks.
- ____ ____ Weight loss <10% in past 3 months.
- ____ ____ Forced expiratory volume in 1 second (FEV1) ≥1 L or ≥35% of predicted.
- ____ ____ Locally advanced NSCLC stages IIIA/IIIB not considered resectable. Patients with stage IV disease are not eligible.
- ____ ____ The following laboratory values obtained ≤21 days prior to registration. Earliest laboratory test date ____-____-____; latest laboratory test date ____-____-____. NOTE: These dates pertain to the following labs only.
 - ____ ____ • ANC ≥1500/mL. ANC = _____.
 - ____ ____ • PLT ≥100,000/mL. PLT = _____.
 - ____ ____ • Total bilirubin ≤1.5 x UNL or direct bilirubin ≤1.5 x UNL.
 - Which was done?**
 - ____ Both Total and Direct bilirubin → Complete both total and direct bilirubin values below.
 - ____ Total bilirubin → Total bilirubin = _____; UNL = _____.
 - ____ Direct bilirubin → Direct bilirubin = _____; UNL = _____.
 - ____ ____ • AST ≤3 x UNL. AST = _____; UNL = _____.
 - ____ ____ • Creatinine ≤1.5 x UNL. Creatinine = _____; UNL = _____.
- ____ ____ **Is this patient a woman of childbearing potential?** (This question may be answered yes or no.)
 - ____ Yes → Complete; Negative serum pregnancy test ... question
 - ____ No → Skip; Negative serum pregnancy test ... question
- ____ ____ Negative serum pregnancy test done ≤7 days prior to registration, for women of childbearing potential only. Negative serum pregnancy test date ____-____-____.

All responses in above section must be “Yes.”

Contraindications:

- ____ ____ Any of the following:
 - Pregnant women
 - Nursing women
 - Men or women of childbearing potential or their sexual partners who are unwilling to employ adequate contraception (condoms, diaphragm, birth control pills, injections, intrauterine device [IUD], or abstinence, etc.) as this regimen may be harmful to a developing fetus or nursing child

NOTE: This study involves an investigational agent whose genotoxic, mutagenic and teratogenic effects on the developing fetus and newborn are unknown.
- ____ ____ Any of the following prior therapies:
 - Prior radiation therapy to the chest
 - Prior systemic chemotherapy for NSCLC (phase II portion)
- ____ ____ New York Heart Association classification III or IV (see Appendix II).
- ____ ____ Any other severe underlying diseases which are, in the judgment of the investigator, inappropriate for entry into this study.
- ____ ____ Uncontrolled infection.
- ____ ____ Major surgery or unhealed wound ≤2 weeks prior to registration. Major surgery date ____-____-____ vs. not applicable ____.

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Eligibility Check – (*Contraindications continued*)

Yes No

- ____ ____ Prior history of malignancy ≤ 5 years, except for adequately treated basal cell or squamous cell skin cancer, adequately treated noninvasive carcinomas (carcinoma in situ), or localized prostate cancer.
- ____ ____ Peripheral neuropathy \geq grade 2.

All responses in above section must be “No.”

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 ____-____-____.
- Is this an USA institution?** (This question may be answered yes or no.)
- ____ Yes \rightarrow Complete authorization question below.
- ____ No \rightarrow Check “not applicable (**Non-USA institution only**)” and go to next question.
- ____ ____ 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 ≤ 21 days after registration.
- ____ ____ Treatment start date ____-____-____.
- ____ ____ Pretreatment tests/procedures must be completed ≤ 21 days prior to registration (see Section 4.0). Earliest pretreatment test date ____-____-____; latest pretreatment test date ____-____-____. NOTE: The earliest pretreatment test date must be less than or equal to the earliest laboratory test date **and** the latest pretreatment test date must be greater than or equal to the latest laboratory test date.
- Exceptions to the above dates:**
- Tumor measurement ≤ 30 days prior to registration (see Section 4.0). A CT chest to include the liver and adrenals are required for baseline evaluation, 4 wks following RT, 3 months following RT, and every 3 months after that for a maximum of 2 years during the observation phase.
- ____ ____ Tumor measurement date ____-____-____.
- ____ ____ All required baseline symptoms must be documented and graded.
- ____ ____ 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.”

- ____ ____ An optional translational research component is part of this study, there will be an option to select if the patient is to be registered onto this component (Section 14.0).
- Patient has given permission to give their tissue sample for research testing.
- ____ ____ At the time of registration, the following will also be recorded:
- ____ ____ Patient has given permission to store sample(s) for future research of cancer.
- ____ ____ Patient has given permission to store sample(s) for future research to learn, prevent, or treat other health problems.
- ____ ____ Patient has given NCCTG permission to give their sample(s) to outside researchers.

Responses in above section may be “Yes” or “No.”

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Grouping Factor

Component

NA Phase I patients not receiving MTD (*As of Addendum 12, the Phase I portion of the study is complete*)

_____ Phase I patients receiving MTD + Phase II patients

Descriptive Factors

Pretreatment supraclavicular involvement

_____ Yes

_____ No

Maximum pre-treatment tumor size (cm)

_____ <3

_____ 3-6

_____ >6

Weight loss in past 3 months

_____ <5%

_____ 5 - <10%

Diabetes

_____ No

_____ Type I

_____ Type II

Dose Level

X 6

Assigned Treatment

_____ A) PS-341 + TAXOL + CBDCA + RT

Person registering Signature _____ Registration Office specialist initials _____

Physician Signature _____ Date (mm/dd/yyyy) __ __/__ __/__ __ __