

North Central Cancer Treatment Group

Coordinating Group = NCCTG: N0724  
SWOG: N0724

N0724: A Randomized Phase II Study of Oligometastatic Stage IV Non-Small Cell Lung Cancer (NSCLC) Treated with Systemic Therapy plus Either Radiotherapy to all Sites of Gross Residual Disease or No Radiotherapy

Addendum 3 – April 30, 2010

**Summary**

- In order to enhance accrual, patients being treated in any manner for brain metastases will now be eligible for this trial.
- Administrative/editorial changes.

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

**Title page** Updated to reflect Addendum 3 and revised NCI version date.

**Protocol Resources**

Page 2: **Kristine M. Hacker, R.N.** replaces ~~Dianne M. Herrera, R.N.~~ as the NCCTG Research Base Nurse.

**Section 1.0** **Background**

Page 7: As a result of now allowing patients being treated for brain metastases, Section 1.19d has been revised as follows:

For patients with brain metastases as a site of oligometastatic disease, surgical resection or radiosurgery appear to prolong patient survival.<sup>19, 20</sup> However, the focus of this study is to assess whether the addition of modest doses of RT to areas of gross disease will enhance the survival of patient when administered in addition to chemotherapy. Thus, patients with brain metastases will be ~~excluded~~ **included only if there were 3 lesions or fewer and they have been successfully treated without evidence of progression prior to registration on this trial.**

**Section 3.0** **Patient Eligibility**

Page 8: As a result of now allowing patients being treated for brain metastases, Section 3.16 has been revised and Section 3.17 is newly added as follows:

3.16 M1 with 1-3 **non-brain** metastases but not more. Note: Patients with M1 disease that is other intrapulmonary metastases can be treated as long as the lung V20 is  $\leq 40\%$ .

**3.17 Patients who have had up to 3 brain metastases can participate if these have been treated prior to registration and there are no signs of progression at the time of registration.**

Page 9: Section 3.41 has been revised for clarification as follows:  
History of > **3** or current brain metastases **or progressive brain metastases if fewer than 3.**

**Section 4.0** **Test Schedule**

Page 11: The “Arm B only:” column heading has been revised for clarification as follows:  
Arm B only: Weekly ~~for 6 weeks~~ during RT

**Section 5.0** **Stratification Factors**

Page 12: Section 5.4 has been revised for clarification as follows:  
Histology: **Predominantly Ssquamous cell vs. adenocarcinoma not predominantly squamous cell NSCLC.**

**Section 12.0** **Descriptive Factors**

Page 29: As a result of now allowing patients being treated for brain metastases, Section 12.4 is newly added as follows:  
**Brain metastases: Yes vs. no.**

**Section 18.0** **Records and Data Collection Procedures**

Page 38: The address for the NCCTG Operations Office has been corrected in the first sentence of Section 18.1 as follows:  
...RO\_FF\_03\_274-CC/NW Clinic...

**Appendix I** **Consent Form**

Page 5: The first two paragraphs under “What are the costs of taking part in this research study” section have been revised for clarification as follows:

~~You and/or your health plan will need to pay for all costs associated with this treatment. You and/or your health plan may also have to pay for other drugs or treatment that are given to help control side effects as well as the cost of tests or exams to look at possible side effects.~~

You and/or your health plan/ insurance company will need to pay for some or all of the costs of treating your cancer in this study. **You and/or your health plan may also have to pay for other drugs or treatment that are given to help control side effects as well as the cost of tests or exams to look at possible side effects.** Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.