

NCI COOPERATIVE GROUP RANDOMIZATION CHECKLIST

04/17/2009

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N0574: Phase III Randomized Trial of the Role of Whole Brain Radiation Therapy in Addition to Radiosurgery in Patients with One to Three Cerebral Metastases

Has the patient ever been on a prior study entered through this Registration Office? Yes

If yes: Prior protocol number N0574; prior study patient ID number _____

NCCTG Patient ID (provided at time of Preregistration) _____
Patient Medical Record Number _____
Participating Group Code (Cooperative Group where credit will be applied) _____
Randomization Institution Name (treating location/performance site) _____
Credentialed SRS Institution Name _____
Institution Code (CTEP assigned number) (not required for NCCTG Members) _____
Physician of Record _____ RT Physician of Record _____
IRB/REB approval date (mm/dd/yyyy) ___/___/___
Date of Randomization (mm/dd/yyyy) ___/___/___
Person Completing Form:
Last Name: _____
First Name: _____
Phone: _____
Fax: _____
Email: _____

Patient initials (last, first, middle) _____
(For Mayo Rochester patients, include first four letters of last name.)
Gender (check one) ___ Male ___ Female ___ Unknown
Patient's Date of Birth (mm/dd/yyyy) ___/___/___
Patient's Zip code (USA) _____
Country of Residence (if not USA) _____
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 data not available
___ Unknown: Patient is unsure of race
Ethnicity (check one)
___ Not Hispanic or Latino
___ Hispanic or Latino
___ Not reported: Patient refused or data not available
___ Unknown: Patient is unsure of their ethnicity
Weight (kg) _____
Performance Status _____
0=fully active (Karnofsky 90-100)
1=ambulatory, capable of light work (K 70-80)
2=in bed <50% of time, capable of self care but not work activities (K 50-60)

NCCTG Patient ID _____

Eligibility Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be mm/dd/yyyy.

Required Characteristics

Yes No NA

Planning MRI confirmed one to three lesions. Each lesion must measure <3.0 cm in maximal extent on the contrasted planning MRI brain scan. NOTE: The pre-registration MRI scan may be used for the planning scan if obtained ≤14 days prior to randomization.	_____ _____
Negative urine or serum pregnancy test done ≤7 days prior to randomization, for women of childbearing potential only. If not a woman of childbearing potential or male (<i>check NA</i>) If a woman of childbearing potential - Negative urine or serum pregnancy test date ____ - ____ - ____	_____ _____

All responses in above section must be “Yes” unless specified as “NA.”

Registration Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be mm/dd/yyyy.

Yes No NA

Treatment on this protocol must commence at the accruing membership under the supervision of an NCCTG or CTSU member physician.	_____
Treatment cannot begin prior to randomization and must begin ≤7 days after randomization.	_____
Tests/procedures must be completed ≤14 days prior to randomization (see Section 4.0 for further details). Note: Quality of Life; Functional independence; and Neurocognitive tests completed after informed consent and prior to randomization. Date of consent (from pre-registration checklist) ____ - ____ - ____. NOTE: These dates are for the Quality of Life; Functional independence; and Neurocognitive test only. The negative serum or urine pregnancy test date is collected in the Required Characteristics above. Earliest test/procedure date ____ - ____ - ____; latest test procedure date ____ - ____ - ____	_____

All responses in above section must be “Yes” unless specified as “NA.”

Stratification Factors

Age (years)	Extracranial disease controlled (months)	Number of Brain Metastases
____ 18 to 59	____ ≤3	____ 1
____ ≥60	____ >3	____ 2
		____ 3

Assigned Treatment

____ A) SRS
 ____ B) SRS + WBRT

Person registering Signature _____ Registration Office specialist initials _____

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