SUMMARY OF CHANGES
Update: July 15, 2008
(Broadcast date: July 15, 2008)

RTOG 0614, A Randomized, Phase III, Double-Blind, Placebo-Controlled Trial of Memantine for Prevention of Cognitive Dysfunction in Patients Receiving Whole-Brain Radiotherapy

Study Chair: Paul D Brown, MD, 507-284-2949, brown.paul@mayo.edu

RTOG 0614 has been updated to clarify drug ordering information as follows:

Section 6.1: The third sentence "For patient eligibility, patients should only be registered and randomized if there is sufficient time to ensure study drug can be available by day 3 of WBRT" was made boldface for emphasis.

Section 7.3.1.1: The first two sentences of the description of the memantine were deleted because they were not accurate for this study.

Section 7.3.2: In the third paragraph, the logistics for drug shipment were updated: the entire 24-week supply of drug will be shipped 2nd day courier. The second and third to last sentences of the paragraph were deleted as they do not apply.

Note: This is an editorial/administrative change to the Protocol. NCI now requires that these changes be documented on the Protocol title page with the date of the update noted as "Update Date", not as a revision."
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RTOG 0614 has been updated as follows:

Sections 1.4, 11.3, 13.5.3.3: "19-item" was corrected to "23-item" in reference to concerns relevant to patients with brain tumors subscale of the FACT-Br.

Appendix VI: Under "STEP 1 - EXAMINER APPROVAL FOR RTOG 0614," in the last sentence of number (5), RTOG was changed to CTSU for consistency with current submission procedures.

Appendix VII: In the box at the end of the worksheet, the fax number for Drs. Meyers and Wefel to use was changed from RTOG to CTSU for consistency with current submission procedures.

Note: This is an editorial/administrative change to the Protocol. NCI now requires that these changes be documented on the Protocol title page with the date of the update noted as "Update Date", not as a revision."
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RTOG 0614 has been updated as follows:

Title Page: Jeffrey S. Wefel, PhD has been added as a neurocognitive co-chair to this study. In addition to the title page, his contact information and name were added as necessary throughout the protocol: Sections 5.1, 11.2.1, Appendices VI, VII.

Eligibility Checklist: Question # 4 of questions to be asked at study registration was revised to request the date the patient provided consent.

Section 1.3: In the sixth and eighth paragraphs, the REFERENCES to RTOG 0212 were updated to RTOG 0525. "Revised" or "R" was added to Hopkins Verbal Learning Test or HVLT throughout this section as well as Sections 2.0, 11.2.2, 12.1, and 13.0 to clarify the version of the test being used.

Section 1.3.1: In the first sentence, "immediate" was changed to "free" recall to correspond with the parts of the HVLT-R per Appendix VI. This change was made throughout the protocol. "15" was deleted in the second sentence as well as in Section 11.2.2.

Section 2.2.2: This was updated as free recall, delayed recall, and delayed recognition to correspond with the parts of the HVLT-R per Appendix VI. These have been changed also in Section 13.0.

Section 5.3.1: The web link was updated under the first bullet.

Section 7.3.2: The second paragraph was updated to indicate that the use of drug(s) in this protocol meet the criteria for IND exemption. The contact information for I.V. Solutions was updated.

Section 7.7: "MedDRA, version 9.0" was added to the first sentence for clarification.

Section 10: As a result of the relocation of the Biospecimen Resource to the University of California San Francisco, the updated information was incorporated throughout this section as well as in Appendices VIII, IX, and X.
Section 11.2.1: Directions for accessing the website for neurocognitive training were added to the second sentence. This was added also to Appendix VI, Step 1, # 2.

Section 12.1: Form PF was deleted as only form FACT-Br (PQ) will be required.

Section 13.5.3.3: The typo, "23-item" was corrected to "19-item."

Appendix V: Instructions for the Study Agent Shipment Form have replaced the actual form, which is posted on the RTOG website.

Appendix VI: A new last sentence was added to # 2 under Step 2 (Alternate Test Forms/Versions) for clarification. Under Step 3, under # 3 (COWAT), "Recording and Scoring" was reworded for clarity. "Requirements for examiner approval" at end of appendix were deleted as they were a duplicate of those already given.

Appendix VII: The cross reference to Section 11.2 was corrected.