SUMMARY OF CHANGES
Amendment 5, Version Date: March 24, 2010
Broadcast: 4/6/10

RTOG 0239, "A Phase II Study Of Accelerated High Dose Thoracic Irradiation With Concurrent Chemotherapy For Patients With Limited Small Cell Lung Cancer"

Study Chair: Ritsuko Komaki, M.D., (713) 792-3420, rkomaki@mdanderson.org

As mandated by CTEP, RTOG 0239 has been amended to replace CTC version 2.0 with the CTEP Active Version of CTCAE. Changes were made to the following sections:

- Section 6.5.1
- Section 7.5.1
- Appendix V: Sections "B", "D", and "E"
SUMMARY OF CHANGES
Amendment 4, Version Date: October 10, 2005

RTOG 0239, “A Phase II Study Of Accelerated High Dose Thoracic Irradiation With Concurrent Chemotherapy For Patients With Limited Small Cell Lung Cancer”

Study Chair: Ritsuko Komaki, M.D., (713) 792-3420, rkomaki@mdanderson.org

Section 3.2.6 was changed to “Previous (within the past 2 years) or concurrent malignancy other than curatively treated basal or squamous cell skin cancer or non-invasive in situ malignancies.”

An amended protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
RTOG 0239, “A Phase II Study Of Accelerated High Dose Thoracic Irradiation With Concurrent Chemotherapy For Patients With Limited Small Cell Lung Cancer”

Study Chair: Ritsuko Komaki, M.D., (713) 792-3420, rkomaki@mdanderson.org

RTOG 0239 has been amended as follows:

Title page: The contact information for Dr. Komaki was updated.

The address for RTOG Headquarters was updated in Sections 7.5.3.5, 7.5.5, and 12.0.

An amended protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
SUMMARY OF CHANGES
Revision 2, Version Date: May 20, 2004

RTOG 0239, “A Phase II Study Of Accelerated High Dose Thoracic Irradiation With Concurrent Chemotherapy For Patients With Limited Small Cell Lung Cancer”

Study Chair: Ritsuko Komaki, M.D., (713) 792-3420, rkomaki@mdanderson.org

RTOG 0239 has been revised as follows:

Section 6.3.7: The maximum dose to the spinal cord was revised from “36 Gy” to “36 Gy to 100%; 40 Gy to 50% (10 cm of the spinal cord can receive up to 45 Gy and 5 cm can receive up to 50 Gy). The spinal cord should not be irradiated BID”.

Spinal cord injury has not been seen on RTOG 94-10 (Arm 2), 45 Gy delivered by 1.8 Gy/Fx/day over 5 weeks with vinblastine and cisplatin or on RTOG 94-10 (Arm 3), 45 Gy delivered by 1.2Gy/Fx, BID, over 3 & ½ weeks with concurrent oral etoposide and cisplatin, with minimal follow up for 24 months. The proposed 40 Gy to 50% of the spinal cord given in daily doses of 1.8Gy/Fx up to 28.8 Gy (to minimize risk of radiation myelopathy, the spinal cord should be spared from the 1.8 Gy/Fx, BID radiation) should be well tolerated with concurrent etoposide and cisplatin. Since the majority of small cell lung cancer lesions are located centrally, it is difficult to avoid delivering less than 36 Gy to the spinal cord.

Section 11.1:

- The SMA-12 was added to the table before each course of chemotherapy to correspond with Section 11.2.3. Footnote “i” was added to specify the SMA-12 assessments;
- A urinalysis was added to the table before each course of chemotherapy to correspond to Section 11.2.3;
- Footnote “f” was revised to clarify that a CT of the chest is done in follow up every 6 months for 3 years;
- Footnote “h” was revised to correspond to the follow-up schedule specified in Section 12.1.

Appendix I, the sample consent: In “What Is Involved In The Study?”, under the “tests and procedures”,

- The second bulleted item was corrected to “Blood tests before beginning treatment...”;
- In the fourth bulleted item, the schedule of the CT of the chest was revised to correspond to Section 11.1.
A revised protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
RTOG 0239, A Phase II Study Of Accelerated High Dose Thoracic Irradiation With Concurrent Chemotherapy For Patients With Limited Small Cell Lung Cancer

Study Chair: Ritsuko Komaki, M.D., (713) 792-3420, rkomaki@mdanderson.org

RTOG 0239 has been updated as follows:

Due to software difficulties, some of changes made in Revision 1 did not appear correctly in the protocol. The following sections have been corrected:

- The units of measurement for cisplatin and etoposide were corrected to “mg/m²” in the third paragraph of Section 1.0 and in Sections 7.1.3 and 7.1.4;
- Section 7.1.8 - “CDDP” was replaced by “cisplatin”.

Section 7.1.4 — In the second sentence, “a patient who is 1.7 m² Body Surface Area (BSA)” was clarified to “a patient whose Body Surface Area (BSA) is 1.7 m²”.

NOTE: This is an editorial/administrative change to the protocol. NCI requires that these changes be documented on the protocol title page as “Update Date”, not as a revision.

A revised protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
SUMMARY OF CHANGES
Revision 1, Version Date: October 29, 2003

RTOG 0239, “A Phase II Study Of Accelerated High Dose Thoracic Irradiation With Concurrent Chemotherapy For Patients With Limited Small Cell Lung Cancer”

Study Chair: Ritsuko Komaki, M.D., (713) 792-3420, rkomaki@mdanderson.org IRB

Review Requirements:
( ) Full board review required
(X) Expedited review allowed, but site IRB requirements take precedence.
( ) No review required

RTOG 0239 has been revised as follows:

Schema page:

- Under “Concurrent Chemotherapy”, the units of measurement for cisplatin and etoposide were corrected to “mg/m²”; this correction also was made in the third paragraph of Section 1.0 and in Sections 7.1.3 and 7.1.4;
- The “Dose Schedule” was reformatted for clarity.

Section 7.1.2 — The units of measurement were corrected from “Meq” to “mEq”.

Section 7.1.4 — In the second sentence, “1.7 M²” was revised to “1.7 m² Body Surface Area (BSA)”.

Section 7.1.7 — The dose of G-CSF was corrected from “5 mg/kg/d” to “5 mcg/kg/d”.

Section 7.1.8 — “CDDP” was replaced by “cisplatin”.

A revised protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
SUMMARY OF CHANGES
Update Date: October 3, 2003

RTOG 0239, “A Phase II Study Of Accelerated High Dose Thoracic Irradiation With Concurrent Chemotherapy For Patients With Limited Small Cell Lung Cancer”

Study Chair: Ritsuko Komaki, M.D., (713) 792-3420, rkomaki@mdanderson.org

RTOG 0239 has been updated as follows:

Schema Page — Corrected typo in second sentence of “Radiation Therapy”. Paragraph should read as follows:

On days 23-26, BID: use AP/PA fields in a.m. @ 1.8 Gy per fraction; boost with 2nd treatment in p.m. @ 1.8 Gy per fraction;

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.

An updated protocol is available (no password required) on the RTOG website: http://www.rtog.org/
SUMMARY OF CHANGES

Update Date: June 20, 2003

RTOG 0239, “A Phase II Study Of Accelerated High Dose Thoracic Irradiation With Concurrent Chemotherapy For Patients With Limited Small Cell Lung Cancer”

Study Chair: Ritsuko Komaki, M.D., (713) 792-3420, rkomaki@mdanderson.org

RTOG 0239 has been updated as follows:

Eligibility Checklist, page 2 — Questions 17, 18, and 19 were added to this operational/demographic portion of the checklist.

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.

An updated protocol is available (no password required) on the RTOG website: http://www.rtog.org/