RTOG 0319, “A Phase I/II Trial To Evaluate Three Dimensional Conformal Radiation Therapy (3D-CRT) Confined To The Region Of The Lumpectomy Cavity For Stage I And IIA Breast Carcinoma”

Study Chair: Frank Vicini, MD, 248-551-1219, fvicini@beaumont.edu

RTOG 0319 – Section 11.3.1 updated to make consistent with Section 11.1 footnote g. The updated sentence has changed to “Cosmesis will be graded by the patient, the radiation oncologist, and the surgeon three, six, and twelve months from the start of therapy and at yearly intervals thereafter.”

NOTE: These are editorial/administrative changes 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: May 21, 2004

RTOG 0319, “A Phase I/II Trial To Evaluate Three Dimensional Conformal Radiation Therapy (3D-CRT) Confined To The Region Of The Lumpectomy Cavity For Stage I And IIA Breast Carcinoma”

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RTOG 0319 has been updated as follows to make the wording in Sections 11.1, 11.3.1, 13.1.3, and the Consent consistent with each other:

Section 11.1: Updated table to make cosmesis grading at three, six and twelve months. Corresponding changes also made in Sections 12.1 and Appendix I under “What is Involved In The Study”, “During follow-up.”

Section 13.1.3: In the first sentence, changed “both the physician and the patient” to read “the radiation oncologist, the surgeon, and the patient”.

NOTE: These are editorial/administrative changes 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 0319 has been updated as follows:

Section 11.1 and 11.3.1: Updated to make cosmesis grading consistent with three, six and twelve months, as stated in Section 13.1.3.

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/
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RTOG 0319 has been updated as follows:

Section 12.1 Summary of Data Submission: The following two forms were added after Pathology Report (P1): Surgical Operative Report (S2) and Surgical Pathology Report (S5).

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: January 14, 2004

RTOG 0319, “A Phase I/II Trial To Evaluate Three Dimensional Conformal Radiation Therapy (3D-CRT) Confined To The Region Of The Lumpectomy Cavity For Stage I And IIA Breast Carcinoma”

Study Chair: Frank Vicini, MD, 248-551-1219, fvicini@beaumont.edu

RTOG 0319 has been updated as follows:

Section 11.2.1 — The parenthetical statement corrected to read “except LCIS”.

NOTE: This is an editorial/administrative change to the protocol. NCI requires that these changes be documented on the protocol title page noted as “Update Date”.

An updated protocol is available (no password required) on the RTOG website: http://www.rtog.org
SUMMARY OF CHANGES
Revision 1, Version Date: September 30, 2003

RTOG 0319, “A Phase I/II Trial To Evaluate Three Dimensional Conformal Radiation Therapy (3D-CRT) Confined To The Region Of The Lumpectomy Cavity For Stage I And IIA Breast Carcinoma”

Study Chair: Frank Vicini, MD, 248-551-1219, fvicini@beaumont.edu

IRB Review Requirements:
( ) Full board review required
(X) Expedited review allowed; however, cite IRB requirements take precedence
( ) No review required

Patients with 1-3 positive nodes are eligible for this protocol, but the AJCC TNM Staging in the current version of the protocol does not match this wording. Thus, RTOG 0319 has been revised as follows (Also, additional wording changes to sections 6 and 12 for clarity):

Protocol Title: A Phase I/II Trial to Evaluate Three Dimensional Conformal Radiation Therapy (3D-CRT) Confined to the Region of the Lumpectomy Cavity For Stage I and II Breast Carcinoma (the "A" has been removed from Stage IIA)

Eligibility List: The previous wording, “AJCC Stage I or IIA (T1N0, T2N0); lesion $< 3$ cm” was changed to “AJCC Stage I or II (T1N0, T1N1, T2N0, T2N1); lesion $< 3$ cm”

Eligibility List: Negative post-tylectomy mammogram (if applicable); no diffuse suspicious microcalcifications.

Eligibility List: Patients with up to 3 positive axillary nodes are eligible. (Made this criterion a separate entry instead of being part of the one above)

Section 3.1.2: The previous wording, “AJCC Stage I or IIA (T1N0, T2N0) histologically confirmed invasive carcinoma of the breast with a lesion $\leq 3$ cm treated with tylectomy and axillary dissection (see Section 8.0)” was changed to “AJCC Stage I or II (T1N0, T1N1, T2N0, T2N1) histologically confirmed invasive carcinoma of the breast with a lesion $\leq 3$ cm treated with tylectomy and axillary node dissection with at least 6 nodes sampled or sentinel node biopsy. Patients with up to 3 positive axillary nodes are eligible (see Section 8.0)”

Section 6.1: New paragraph added at the end of this section:

The PTV is saved and is used to generate the beam aperture, (with an additional margin to take penumbra into account). Since a substantial part of the PTV often extends outside the patient (especially for superficial cavities) the PTV is then copied to a PTV for
Evaluation (PTV_EVAL), which is edited: This PTV is limited to exclude the part outside the patient and the first 5 mm of tissue under the skin (in order to remove most of the build up region for the DVH analysis) and excluding (if applicable) the PTV expansion within the lung. This PTV_EVAL is the structure used for DVH constraints and analysis (see Section 6.8.2). This PTV for evaluation CANNOT be used for beam aperture generation.

Section 6.8.1: The following sentence deleted: The ITC will compare submitted DVHs for the PTV, designated critical structures, and unspecified tissues. The following sentence added to replace it: “**The ITC will compare submitted DVHs for the PTV for Evaluation (see definition of the PTV for Evaluation, Section 6.1), designated critical structures, and unspecified tissues.**

Eligibility Checklist, page 1, #2: The previous wording, “Is the AJCC TNM classification T1-2, N0, M0?” was changed to “**Is the AJCC TNM classification T1-2, N0-N1, M0?**”

Section 12: The Surgery form (S1) and the long-term form (FF) are being deleted.

Section 12.2.1: ITC phone number fixed.

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