SUMMARY OF CHANGES
Update: June 14, 2012
(Broadcast 6/14/12)

RTOG 0244, “A Phase II Study of Submandibular Salivary Gland Transfer to the Submental Space Prior to Start of Radiation Treatment for Prevention of Radiation-Induced Xerostomia in Head and Neck Cancer Patients”

Study Chair: Naresh Jha, M BBS, (780) 432-8755, nareshj@cancerboard.ab.ca

RTOG 0244 has been updated as follows:

Long-term follow up has been revised from 5 years to the current RTOG standard of follow up for the patient’s lifetime. The following sections have been revised for this change:

- **Section 11.1**: Footnote "i";
- **Section 12.1**: The schedule for the Follow-up Form (F1);
- **Appendix I**:
  - The schedules for “Physical examination” and “Evaluation for Side Effects” in the table under “What Is Involved in the Study”;
  - The 1st paragraph under “How Long Will I Be in the Study?”.

Other Changes

**Title page**: “Study Chairs” was updated to the current RTOG standard, “Study Team”, and the Senior Statistician for the study was added.
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As mandated by CTEP, RTOG 0244 has been amended to replace CTC version 2.0 with the CTEP Active Version of CTCAE. Changes were made to the following sections:

- Section 6.8
- Section 13.2, 4th paragraph
SUMMARY OF CHANGES  
 Amendment 4, Version Date: March 2, 2006

RTOG 0244, "A Phase II Study of Submandibular Salivary Gland Transfer to the Submental Space Prior to Start of Radiation Treatment for Prevention of Radiation-Induced Xerostomia in Head and Neck Cancer Patients"

Study Chair: Naresh Jha, M.BBS., (780) 432-8755, nareshj@cancerboard.ab.ca

RTOG 0244 was amended to clarify that patients with a suspicious neck node (on CT or MRI scan) on the contralateral neck or the side chosen for salivary gland transfer are ineligible for the study. This information was added to Section 3.2.1 and as question 9 on page 1 of the Eligibility Checklist (subsequent questions were appropriately renumbered).

An amended protocol is available on the RTOG Web site, www.rtog.org
RTOG 0244, "A Phase II Study of Submandibular Salivary Gland Transfer to the Submental Space Prior to Start of Radiation Treatment for Prevention of Radiation-Induced Xerostomia in Head and Neck Cancer Patients"

Study Chair: Naresh Jha, M.BBS., (780) 432-8755, nareshj@cancerboard.ab.ca

RTOG 0244 has been amended as follows:

Title page: The 800 number for RTOG Headquarters was added.

Eligibility Checklist:

- On page 1, Questions 13 and 14 were added, and Question 15 was amended for clarity and to ensure that all required pre-treatment evaluations are completed. The subsequent question was appropriately renumbered.
- In the paragraph at the bottom of page 2, the phrase, "prior to calling RTOG", was updated to "prior to web registration" to be current with RTOG standard.

Section 5.2: The heading and text were updated to current RTOG standard for registration procedures.

Section 6.5.1: In the first sentence of the third paragraph, the number of fractions was corrected from 22 to 27.

Section 6.8.3: The NCI mandated text for adverse event reporting requirements was added. The prior text in this section was deleted and the prior Section 6.8.4 was deleted.

An amended protocol is available on the RTOG Web site, www.rtog.org
SUMMARY OF CHANGES
Update: August 4, 2004

RTOG 0244, “A Phase II Study of Submandibular Salivary Gland Transfer to the Submental Space Prior to Start of Radiation Treatment for Prevention of Radiation-Induced Xerostomia in Head and Neck Cancer Patients”

Study Chair: Naresh Jha, M.BBS., (780) 432-8755, nareshj@cancerboard.ab.ca

RTOG 0244 has been updated as follows:

Section 12.1 – The instructions, “*NOTE: CD must be submitted to RTOG Headquarters; see Section 11.3.3.3 for details”, were added for clarity regarding submission of Salivary Scans (C6).

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

An updated protocol is available (no password required) on the RTOG website: www.rtog.org
SUMMARY OF CHANGES
Revision 2, Version Date: July 21, 2004

RTOG 0244, “A Phase II Study of Submandibular Salivary Gland Transfer to the Submental Space Prior to Start of Radiation Treatment for Prevention of Radiation-Induced Xerostomia in Head and Neck Cancer Patients”

Study Chair: Naresh Jha, M.BBS., (780) 432-8755, nareshj@cancerboard.ab.ca

RTOG 0244 has been revised as follows:

Title page:
- Samuel Ryu, M.D. is now the Quality of Life Co-Chair;
- The 800 number was deleted, as the number is not current.

Section 4.6: The timeframe for the dental evaluation was revised from “four weeks prior to study entry” to “within 3-4 weeks prior to start of radiation therapy”. This change also was made in Section 11.1.

Section 7.0: The sentence, “the choice of chemotherapy is at the discretion of the treating physician”, was added for clarity. In addition, the text of Section 7.0 also was added as Section 9.1 for clarity (and the subsequent section was appropriately numbered).

Sections 11.3.3.3 and 12.0 were updated with the new RTOG Headquarters address.

In Appendix I, two risks associated with radiation therapy were re-categorized. The risk of dryness of mouth and altered taste was changed from “Very Likely” to “Less Likely”. The risk of permanent hair loss was changed from “Less Likely But Serious” to “Less Likely”.

A revised protocol is available (no password required) on the RTOG Web site, www.rtog.org
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IRB Review Requirements:
( ) Full board review required
( ) Expedited review allowed; however, site IRB requirements take precedence.
( ) No review required

RTOG 0244 has been revised as follows:

Section 6.4.1: The phrase, “or d Max depending on the clinical situation and at the discretion of the treating Radiation Oncologist”, was added to the first sentence.

Section 7.0: The following statements were added: “Postoperative chemoradiotherapy is allowed. Neoadjuvant chemotherapy is not permitted.” A corresponding question was added as Question 18 on page 2 (the demographic/operational portion) of the Eligibility Checklist.

Section 8.2.2.1, “Rationale for Neck Dissection On The Side of Transfer”, was added. The citation in this section was added to References, and subsequent citations were appropriately renumbered in References and throughout the protocol.

Section 13.3.1: This section was revised for clarity and a third criterion was added for determining whether or not the surgical transfer was performed per protocol.

Appendix I: In the section “What Is Involved In The Study?”, under “Schedule”, the “CT scan of your belly area” was deleted to correspond with the assessments in Section 11.1.

A revised protocol is available (no password required) on the RTOG Web site, www.rtog.org