

RTOG 0421

For Patients with Locally Recurrent Head and Neck Cancer

RTOG 0421 Available Through the CTSU

A Phase III Trial For Locally Recurrent, Previously Irradiated Head and Neck Cancer:
Concurrent Re-Irradiation and Chemotherapy Versus Chemotherapy Alone

Patient Population

See Section 3.0 for Complete Eligibility Details

- Patients must have pathologically confirmed diagnosis of recurrent or second primary SCC of the oral cavity, oropharynx, hypopharynx, larynx, or recurrent neck metastasis with unknown primary.
- Patients must have measurable disease.
- Patients must be surgically inoperable; patients who have recurred following a past resection must be \geq 3mos post-surgery and be completely healed with no carotid exposure.
- Patients must have had prior RT of 45-75 Gy to $>$ 75% of the present tumor volume.
- Re-irradiation must not lead to a lifetime spinal cord dose of $>$ 54Gy.
- The time from prior RT to first recurrence must be greater than 6mos.
- Patients must be at least 6mos post-RT, chemotherapy, or targeted therapy.
- Patients may have received systemic chemotherapy for initial H&N cancer treatment, but not for recurrent H&N cancer treatment. Prior chemoprevention with COX-2 inhibitors or retinoids is allowed.
- Patients may not have distant metastases.
- Patients may not have any severe, active comorbidities at time of registration (see Section 3.2.5 for list of excluded conditions).

Number of Participants: 240

Treatment Plan

Arm 1—Re-Irradiation + Chemotherapy:

- RT 1.5 Gy given BID 5 days/week during weeks 1, 3, 5, and 7 (total of 60 Gy in 40 fractions)
- Chemo will be given between the BID fractions.
- Paclitaxel 20mg/m² IV 5 days/week during weeks 1, 3, 5, and 7.
- Cisplatin 15mg/m² IV 5 days/week during weeks 1, 3, 5, and 7.
- Filgrastim 300 or 480mcg SC QD starting 24 hours after the final chemo administration of each treatment week x 8 days (given during weeks 2, 4, 6, and 8).

Arm 2—Chemotherapy Alone:

Physician chooses one of the following regimens:

- Cisplatin 100mg/m² IV on Day 1
- 5-FU 1000mg/m²/day CIVI on Days 1-4
- 21-day cycles

Or

- Cisplatin 75mg/m² IV on Day 1
- Paclitaxel 175mg/m² IV on Day 1
- 21-day cycles

Or

- Cisplatin 75mg/m² IV on Day 1
- Docetaxel 75mg/m² on Day 1
- 21-day cycles

At least 6 cycles of chemotherapy are recommended; see Section 7.1.2.4 for details regarding duration of chemotherapy.

RTOG
Protocol Chair:
Stuart Wong, MD

Patient Enrollment

Non-RTOG Members: CTSU Patient Registrar 1-888-462-3009

Protocol Information

CTSU Help Desk 1-888-823-5923, CTSUcontact@westat.com, www.ctsu.org

Please Enroll Your Eligible Patients!

Schema

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R	*Arm 1: Re-irradiation plus Concurrent Chemotherapy
A	Radiation Therapy on weeks 1, 3, 5, and 7
N	1.5 Gy/fx, twice daily x 5 days, 40 fractions, for a total dose of 60 Gy
D	Chemotherapy (cisplatin/paclitaxel) on weeks 1, 3, 5, and 7
O	G-CSF on weeks 2, 4, 6, and 8
M	
I	**Arm 2: Chemotherapy Alone
Z	Select from one of the three standard chemotherapy regimens:
E	cisplatin/5-FU; cisplatin/paclitaxel; cisplatin/docetaxel

*See Sections 6.0 and 7.1.1 for details

**See Section 7.1.2 for details