

Clinical Trials in Supportive Care: Cancer Treatment-Related Mucositis

It is estimated that fewer than 10% of eligible adult patients are enrolled in clinical trials. To encourage referral of patients to these trials, each issue of *The Journal of Supportive Oncology* focuses on current clinical trials in the supportive care topic areas discussed elsewhere in that issue. This month, the editors have selected trials in the management of cancer treatment-related mucositis.

RK-0202 in Preventing Oral Mucositis in Patients Who Are Undergoing Radiation Therapy for Cancer of the Mouth or Throat

Rationale: RK-0202, an oral rinse, may be able to prevent oral mucositis in patients who are undergoing radiation therapy for cancer of the mouth or throat.

Objectives: Compare the efficacy of two different doses of RK-0202 on the incidence, severity, and time to onset of oral mucositis in patients with squamous cell carcinoma of the oral cavity, oropharynx, or nasopharynx who are undergoing radiotherapy • determine the safety and tolerability of RK-0202 in these patients • compare the effect of placebo mouthwash vs standard care in these patients

Study design: Randomized, double-blind, placebo-controlled, parallel-group, multicenter phase II study

Eligibility: Patients 18 years of age and older with histologically confirmed squamous cell carcinoma of the oral cavity, oropharynx, or nasopharynx and scheduled to undergo radiotherapy that would deliver a minimum of 60 Gy over 5–8 weeks to an area of ≥ 2 cm² of at least three oral cavity anatomical sites • radiotherapy must begin within 9 weeks after prior surgery and may consist of a single-daily-dose fractionated regimen (up to 2.2 Gy/d), hyperfractionated regimen (up to

2.4 Gy/d), or concurrent boost (up to 3.3 Gy/d during boost) • Karnofsky performance status 60%–100% • no evidence of oral mucositis at study entry • no T1 or T2 glottic tumors • no prior radiotherapy to the head and neck • no concurrent chemotherapy • no concurrent brachytherapy or interstitial implantation • no topical or oral medications for 30 minutes before and after study drug • no concurrent therapy with amifostine • no other concurrent investigational drugs or concurrent investigational or mucoprotective therapy for the prevention of oral mucositis • no concurrent oral rinsing with hydrogen peroxide, sucralfate, or chlorhexidine gluconate

Sponsors: Jonsson Comprehensive Cancer Center • National Cancer Institute
Protocol IDs: UCLA-0205011 • NCI-G02-2111 • RK-0202:02

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Benzydamine Oral Rinse for the Treatment of Oral Mucositis Resulting From Radiation Therapy for Cancer of the Oral Cavity, Oropharynx, or Nasopharynx

Rationale: The safety and efficacy of benzydamine hydrochloride oral rinse in reducing the risk and duration of severe mucositis, as well as interruptions in cancer treatment related to mucositis, are unknown.

Objective: Determine the safety and efficacy of benzydamine hydrochloride on the incidence and duration of oral mucositis in patients with squamous cell carcinoma of the oral cavity, oropharynx, or nasopharynx who are undergoing radiotherapy

Study design: Randomized, double-blind, placebo-controlled, parallel-group,

multicenter phase III study

Eligibility: Patients 18 years of age and older with pathologically confirmed head and neck cancer of the oral cavity, oropharynx, or nasopharynx and scheduled to undergo a continuous course (eg, 6–8 wk) of conventional or hyperfractionated external-beam radiation, with or without chemotherapy • at least two oral tissue sites (not including areas of previous lesion, tumor, surgical resection, or the lips) must be included in the radiation treatment volume • total planned radiation dose must equal or exceed 5,500 cGy

Sponsor: McNeil Consumer & Specialty Pharmaceuticals

Protocol ID: 00-107

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Light-Emitting Diode Therapy in Preventing Mucositis in Children Receiving Chemotherapy, With or Without Radiation Therapy, Before Bone Marrow Transplantation

Rationale: Light-emitting diode (LED) therapy may be able to prevent oral mucositis in children who are receiving chemotherapy, with or without radiation therapy, before donor bone marrow transplantation

Objective: Compare the incidence and severity of oral mucositis in children undergoing LED therapy during a pre-transplantation myeloablative conditioning regimen (chemotherapy with or without radiotherapy) and continuing through the post-bone marrow transplantation (BMT) phase versus LED therapy during the post-BMT phase only

Study design: Randomized, double-blind, multicenter phase II study

Eligibility: Patients 2–18 years of age

undergoing a myeloablative conditioning regimen comprising chemotherapy, with or without radiotherapy, prior to a first allogeneic BMT • no pulmonary dysfunction that would increase significantly the risk of requiring intubation during the first 21 days after transplantation • no photophobia • no concurrent medication that may cause epidermal or ocular photosensitivity • sufficient maturity to tolerate LED therapy and oral examination without combativeness

Sponsor: Medical College of Wisconsin
Protocol IDs: MCW-HRRC-28600 • MCW-CHW-0070 • NCI-V02-1699

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Acupuncture in Treating Mucositis-Related Pain Caused by Chemotherapy in Patients Undergoing Stem Cell Transplantation

Rationale: Acupuncture may be effective in relieving mucositis-related pain caused by chemotherapy in patients undergoing stem cell transplantation.

Objectives: Compare the efficacy of acupuncture vs placebo acupuncture in alleviating mucositis-related pain secondary to high-dose chemotherapy (as assessed by total cumulative dose of opioids used and subjective pain scores) in patients undergoing hematopoietic stem cell transplantation • compare the overall number of patients requiring opioid ther-

apy in these two intervention groups • compare nausea and vomiting scores of patients in the two groups • compare sedation scores of patients in the two groups • compare use of other psychotropic medications (eg, anxiolytics or hypnotics) by patients in the two groups • compare the need for total parenteral nutrition (TPN) and the number of days on TPN experienced by patients in the two groups • compare pruritus and the need for symptomatic treatment in patients in the two intervention groups

Study design: Randomized, double-blind, placebo-controlled study

Eligibility: Patients 18 years of age and older undergoing hematopoietic stem cell transplantation • directly observed oral or pharyngeal mucositis and/or suspected esophageal mucositis after high-dose chemotherapy • no pain unrelated to mucositis that requires use of potent analgesics prior to initiation of high-dose chemotherapy • no history of bleeding disorders • normal prothrombin time and partial thromboplastin time • no concurrent anticoagulant therapy • no history or evidence of drug addiction or drug-seeking behavior • no skin infection at sites of acupuncture points

Sponsor: National Cancer Institute
Protocol ID: NCI-03-C-0125

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Mucositis in Patients Receiving Radiation Therapy for Cancer of the Mouth, Pharynx, or Larynx

Rationale: Radiation therapy uses high-energy x-rays to damage tumor cells. Giving radiation therapy at different times of the day may affect the chance of developing side effects such as mucositis.

Objective: Compare the toxicity to the oral mucosa of radiotherapy delivered in the morning or late afternoon in patients with squamous cell carcinoma of the oral cavity, pharynx (oropharynx, hypopharynx, or nasopharynx), or larynx receiv-

ing radiation treatment to a significant part of the oral and/or oropharyngeal mucosa

Study design: Randomized, multicenter phase III study

Eligibility: Patients 16 years of age and older with histologically confirmed squamous cell carcinoma of the oral cavity, pharynx (oropharynx, hypopharynx, or nasopharynx), or larynx eligible for radical radiotherapy • disease stage: TX, T1–T4, NX, N0–N3, M0 • no M1 disease • directly visible area of mucosa, including two or more protocol-specified anatomical locations in the radical target volume • at least 6 cm² in area, irrespective of shape • intention to deliver radiotherapy to a radical dose without chemotherapy • no concurrent anticoagulant therapy • prior surgical resection of primary or neck lymph nodes allowed • postoperative macroscopic or microscopic residual disease eligible for radical radiotherapy allowed • patients with completely resected disease who are judged to be at high risk of relapse and who are eligible for radical radiotherapy allowed • Eastern Cooperative Oncology Group (ECOG) performance status 0–1 • hemoglobin ≥ 10 g/dL • granulocyte count ≥ 1,500/mm³ • platelet count ≥ 100,000/mm³ • normal sleeping habits (ie, circadian rhythm) • patients must have had dental assessment and necessary prophylactic dental extractions carried out • no connective tissue diseases • no organic brain syndrome related to chronic alcohol excess or other cause of sufficient severity to preclude cooperation with treatment • no active uncontrolled infection • no history of psychiatric or neurological disorder that would preclude study compliance • at least 6 months since prior chemotherapy • no prior radiotherapy to the head and neck region • no concurrent radio-protective drugs or therapy

Sponsor: National Cancer Institute of Canada

Protocol ID: CAN-NCIC-HN3

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Previous issues of *The Journal of Supportive Oncology* have described the availability of clinical trials in the following supportive care areas:

Cancer Cachexia and Anorexia

November/December 2003, pp 294–295

Chemotherapy-Induced Diarrhea

May/June 2003, p 78

Chemotherapy-Induced Nausea and Vomiting

July/August 2003, p 146

Hot Flashes in Women With Breast Cancer

May/June 2003, p 78

Neuropathic Pain

July/August 2003, p 146

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