



Carolin HealthCare System

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Carolin HealthCare System (CHS) Receives \$8 Million NIH Grant to Conduct First-Ever Study of its Kind

A Multicenter Team to Study Treatment Outcomes from Head and Neck Cancer Therapies

September 26, 2012 –[CHS's](#) Carolinas Medical Center has been awarded an \$8 million grant from the National Institute of Dental and Craniofacial Research (NIDCR) to study dental and oral medicine outcomes of patients who have received high-dose radiation to the head and neck region. This is the largest research grant ever awarded to CHS. As the awardee organization, CHS will administer the grant, which will be shared across the several sites involved in the study. Each year 40,000 Americans develop head and neck cancer, and many have to receive high-dose radiation therapy, often in combination with surgery and/or chemotherapy. An unavoidable side effect of radiation therapy is damage to the oral and maxillofacial tissues, some of which persist for the lifetime of the patient.

These side effects include a permanent decrease in saliva production (hyposalivation), as the major salivary glands are often included in the areas treated with radiation therapy. Hyposalivation has a major impact on patients' overall quality of life and it significantly increases the risk of caries (tooth decay) and tooth loss. Radiation can also impair bone healing, leading to a life-long risk of infection of the bone surrounding the teeth, referred to as osteoradionecrosis (ORN). This can lead to an increased risk of fracture of the jaw and severe pain that requires extensive medical and surgical therapy. It is felt that approximately 50% of all ORN cases are associated with dental extractions following radiation therapy, yet these patients are caught in a vicious cycle as they are at a high-risk of needing dental extractions.

“Currently, dental management of these patients is largely based on expert opinion and there are no evidence-based guidelines available to inform the healthcare team who manage patients before or after radiation therapy,” said Michael Brennan, DDS, MHS, Co-Principal Investigator of this grant. “The data we collect will lead to a better understanding of the oral and dental sequelae experienced by these patients after radiation therapy, which will lead to protocols for patients with head and neck cancer that are based on data from this five year study.”

“This will be a landmark clinical study as it will be the first study to systematically examine dental outcomes in a large population of over 750 patients receiving head and neck radiation therapy,” said Rajesh V. Lalla, DDS, PhD, Co-Principal Investigator of this grant. We expect to not only document the substantial dental morbidity in this population but also identify risk factors for adverse outcomes. This valuable information will have a direct impact on the clinical care of these patients.”

Head and neck cancer patients enrolled in this multi-center study will receive a standard dental assessment prior to radiation therapy, with detailed documentation of dental/oral conditions and dental management at that time. Follow-up visits will be conducted every six months for up to two years for the entire study population. Tooth loss will be

documented and secondary analyses will look for risk factors for tooth loss. This information will allow for definitive documentation of the dental complications in this population, which in turn will guide decision-making and standard of care for pre and post radiation therapy dental management. Patients will be enrolled at the following five sites with the following local investigators leading the effort at each site: Carolinas Medical Center (Dr. Brennan), University of Connecticut Health Center (Dr. Lalla), Harvard University/Dana Farber Cancer Center (Dr. Nathaniel Treister), University of Pennsylvania (Dr. Thomas Sollecito), and New York University (Dr. Brian Schmidt). The University of Minnesota (Dr. James Hodges) will serve as the Data Coordinating Center for this study. As the Co-Principal Investigators on the grant, Dr. Brennan and Dr. Lalla will jointly oversee the overall project.

“The uniqueness of the study, the size of the research grant and the reputation of the multicenter research team provide clear evidence of the leading role academic and clinic research at CHS is achieving, in relation to a multidisciplinary strategy for therapeutic innovation,” said James McDeavitt, MD, Chief Academic Officer of CHS.

Dr. Brennan is the Associate Chairman at CHS’s Department of Oral Medicine and has a major interest and expertise in the management of oral complications of cancer therapy. He is currently President of the International Society of Oral Oncology and recently served as the Chair of the Oral Care Study Group of the Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology (MASCC/ISOO). Through the collaboration of these organizations, he has directed significant research advances in this field, and he has organized two ongoing international studies – OraSTEM and Peds OraSTEM, which are evaluating oral complications in adult and pediatric patients treated with hematopoietic stem cell transplantation.

Dr. Lalla is a tenured Associate Professor of Oral Medicine at the University of Connecticut School of Dental Medicine. He is currently the Chair of the Mucositis Study Group of MASCC/ISOO. He also serves on the Board of Directors of MASCC. Dr. Lalla is a leading international expert on oral complications of cancer therapy, with substantial experience and expertise in clinical research on this topic. His previous research has been funded by the NIH, foundations and industry. He recently led an international effort to update the MASCC/ISOO Clinical Practice Guidelines for mucositis, a common complication of cancer therapy, which involved almost 100 contributors from 24 countries.

About Carolinas Healthcare System

[Carolinash HealthCare System](http://carolinashhealthcare.org) (carolinashhealthcare.org), one of the nation’s leading and most innovative healthcare organizations, provides a full spectrum of healthcare and wellness programs throughout North and South Carolina. Its diverse network of more than 650 care locations includes academic medical centers, hospitals, healthcare pavilions, physician practices, surgical and rehabilitation centers, home health agencies, nursing homes, behavioral health centers, and hospice and palliative care. CHS works to improve and enhance the overall health and wellbeing of its communities through high quality patient care, education and research programs, and numerous collaborative partnerships and initiatives.

About the NIDCR and NIH

The NIDCR is a part of the National Institutes of Health (NIH), which is federally-funded. The mission of the National Institute of Dental and Craniofacial Research (NIDCR) is to improve oral, dental and craniofacial health through research, research training, and the dissemination of health information by:

- Performing and supporting basic and clinical research;
- Conducting and funding research training and career development programs to ensure an adequate number of talented, well-prepared and diverse investigators;
- Coordinating and assisting relevant research and research-related activities among all sectors of the research community;
- Promoting the timely transfer of knowledge gained from research and its implications for health to the public, health professionals, researchers, and policy-makers.