

Cyclooxygenase-2 Inhibition in Radiation-induced Oral Mucositis

Principal Investigators: Dr. Rajesh V. Lalla and Dr. Douglas E. Peterson
Department of Oral Health and Diagnostic Sciences,
University of Connecticut Health Center (UCHC).

Co-Investigators: Dr. Robert J. Dowsett, Division of Radiation Oncology, UCHC.
Dr. Upendra Hegde, Division of Hematology/Oncology, UCHC.
Dr. Carol C. Pilbeam, Dept. of Medicine, UCHC.
Dr. Stephen T. Sonis, Dana Farber Cancer Institute.

Purpose of Research

The purpose of this research study is to test the usefulness of a prescription pain medication in reducing the pain and severity of mouthsores that are likely to develop as a result of your radiation therapy. Another goal of this research is to test whether this drug is helpful in treating the cancer itself. The pain medication to be studied is called celecoxib and is marketed under the brand name Celebrex[®]. This drug has been approved by the U.S. Food and Drug Administration to reduce pain and inflammation in patients suffering from arthritis. It has also been approved to reduce the number of precancerous polyps in the intestine. However, it is not known whether this medication is useful in reducing mouthsores due to radiation or in treating the cancer itself.

General Eligibility Criteria

- Adults aged 18 - 75 who will be receiving at least 5000 cGy radiation therapy to at least 2 of 14 pre-defined areas in the mouth and throat.

Possible benefits from taking part in this study

- The study drug may reduce the pain and severity of your mouthsores.
- The study drug may help in treating your cancer.

Financial Compensation

- You will be compensated \$75 at the end of the study if you complete 90% of study drug doses and 90% of study visits.
- Up to four times during the study you will have the opportunity to give a small blood sample (about 2 teaspoons) and a very small and superficial sample of mouth tissue (about the size of this black circle ● and the thickness of a dime). These samples are optional, you can still take part in this study even if you do not wish to give these samples. If you choose to give a sample, you will be compensated \$25 for each blood sample and \$100 for each tissue sample that you give.

This study will be carried out at the University of Connecticut Health Center where you will be receiving your radiation therapy. For further information, please contact Dr. Lalla or Dr. Peterson at 860-679-2952 or 679-2974.

IRB # 03-157-2 Approved 11/20/2006 valid from 11/20/2006 to 12/10/2007