

14.0 INFORMED CONSENT:

THE UNIVERSITY OF TEXAS



HOUSTON
Health Science Center

Medical School
Departments of Internal Medicine
Division of Oncology

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER – HOUSTON AND HERMANN HOSPITAL INFORMED CONSENT

A PHASE II CLINICAL TRIAL OF CISPLATIN (PLATINOL) FOLLOWED BY GEMCITABINE HLC (GEMZAR) IN COMBINATION WITH MILD, FEVER-RANGE WHOLE- BODY THERMAL-THERAPY (FR-WB-TT) AT 104°F IN PATIENTS WITH ADVANCED MALIGNANCIES

INVITATION TO TAKE PART IN A RESEARCH STUDY:

You are invited to take part in this research study to be conducted by the doctors of The University of Texas Health Science Center – Houston and Hermann Hospital. It is important that you read and understand several general guidelines that apply to all persons who take part in this study. This research study, HSC-MS-04-254 has been reviewed and approved by the Committee for the Protection of Human Subjects for the University of Texas Health Science Center.

You will be one of 54 subjects asked to take part in this open treatment study of the safety and efficacy of a standard chemotherapy cisplatin + interferon- α + gemcitabine (Gemzar) given with mild, fever-range whole-body thermal-therapy (FR-WB-TT; 104 °F). Cisplatin, interferon- α , and Gemzar are all medicines frequently used to treat cancer in cancer-doctor's clinics. The thermal-treatment (FR-WB-TT) is a fever-like treatment that raises your body to a natural fever temperature. This safe temperature increase is similar to the fever that your body may use to help fight a virus illness (such as the flu) or a bacterial illness (like pneumonia). This fever-range whole-body thermal-therapy will be given approximately 36 hours after the chemotherapy drug cisplatin. The Gemzar will be given to you at the same time as the FR-WB-TT. Interferon- α , is a natural substance normally found in your body. Your body normally uses interferon- α to fight viral sicknesses. Interferon- α will be given to you twice daily every day during the whole treatment, beginning the day of giving cisplatin. Cisplatin, Gemzar and interferon α are chemotherapy agents approved by our national Food and Drug Administration (FDA) for the treatment of many forms of cancer. Whole body thermal-therapy (FR-WB-TT) using the Heckel HT 2000 Infrared WBH unit when combined with chemotherapy is an investigational procedure. This means the treatment is approved for limited testing by the FDA, but not in general use.

Taking part in this study is voluntary. You may refuse to take part or withdraw your consent at any time. A decision not to take part will not change the services available to you for further medical care. Your response to treatment decides if you can continue to take part in the study.

PURPOSE OF STUDY:

The purposes of this study are: (1) to find out if there is a tumor response and survival benefit for patients with advanced cancer who receive heat treatments combined with chemotherapy drugs; (2) whether this treatment is well tolerated; and (3) whether it will improve how subjects feel over all.

HSC-MS-04-259

Page Two

ORDERLY WITHDRAWAL FROM THE STUDY:

If you should decide to withdraw your consent and no longer wish to take part in this study, you should do so under a doctor's guidance. Failure to follow the doctor's instructions in this regard may result in worsening of your overall condition and increase the chance of side effects.

TERMINATION OF PARTICIPATION:

You may be removed from this study without your consent, if in the doctor's judgment, it would be for your benefit, or if you fail to follow the study outline for care as explained by the doctor or her associate.

BENEFITS:

While the doctors are using a treatment (cisplatin/interferon- α followed by FR-WB-TT + gemcitabine) thought to be of benefit to you, actual personal benefit may not result from taking part in the study. However, knowledge gained may be of benefit to others.

RISKS AND SIDE EFFECTS:

MILD, FEVER-RANGE WHOLE-BODY THERMAL-THERAPY (FR-WB-TT):

FR-WB-TT has been associated with raised anxiety level due to longer duration of treatment. Patients may also experience fever blisters if they have a history of such disorder, tingling and numbness of fingers and toes, sinus congestion, short term changes in sleep patterns, fatigue, and loss of appetite.

Mild, FR-WB-TT will be performed using a whole-body warming device (the Heckel HT2000 Infrared WB-TT unit) to increase your body temperature to 104 °F, a natural fever temperature. Our national Food and Drug Administration (FDA) considers this device to be safe to treat you.

CISPLATIN: This chemotherapy drug can cause nausea and vomiting, and can injure the kidneys (detected by increase in blood values of blood creatinine and BUN). Cisplatin can cause nerve damage that is experienced as numbness and tingling of the hands and feet, and it can cause a decrease in hearing. Cisplatin may also cause a decrease in white blood cell count and platelet count, which can increase the possibility of infection and bleeding.

GEMCITABINE (GEMZAR): This chemotherapy drug is usually well tolerated. Although we give medicine to prevent nausea, some patients may experience mild nausea and cramps in the abdomen. In some patients, their white blood cell count or platelet count may decrease after receiving gemcitabine, which can increase possibility of infection and bleeding.

INTERFERON- α : This drug can cause fever, chills and cause your muscles to ache, much like the flu. These symptoms can be largely reduced by taking Celebrex (celecoxib) one hour before the interferon shot.

HSC-MS-04-259

Page three

COMPENSATION FOR INJURY:

If you suffer any injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, all needed facilities, emergency treatment and professional services will be available to you, just as they are to the community in general. You should report any such injury to (put the principal investigator's name and phone number here) and to the Committee for the Protection of Human Subjects at 713-500-3985.

FINANCIAL COMPENSATION:

Because the heat treatment is an investigational procedure, one approved for limited testing by the Food and Drug Administration (FDA) but not in general use, Dr. Bull will not charge you a professional fee for performing the treatment. However, all costs for hospital observation, tests, sedation, other medications, routine clinical evaluations by the physician will be billed to you and/or your insurance. Although verification of insurance intent to pay for treatment cost has been done before treatment and discussed with you, you have been advised to personally consult with your insurance company as to whether the cost of this treatment is covered. The responsibility for all treatment costs not paid for by insurance is yours.

CONFIDENTIALITY AND ANONYMITY:

Representatives of the Food and Drug Administration (FDA) and the Committee for the Protection of Human Subjects (CPHS) may review your research and/or medical record for the purpose of verifying data. However, your confidentiality will be preserved within legal limits and the names of patients will not be revealed in any reports or publications resulting from this study.

FOR FURTHER INFORMATION:

Any questions that you may have or that may come up at any time can be answered by Dr. Joan M.C. Bull and her Co-investigators. You may contact her or her associate at (713) 500-6821 or (713) 704-3961. You may also call 713-704-4284 to reach Dr. Bull or her associates at any time, day or night.

BEFORE YOU SIGN THIS DOCUMENT:

By signing this consent, you are voluntarily agreeing to participate in this research study. Make sure that questions have been answered to your satisfaction and that you have a clear understanding of the treatment plan. If you have questions regarding your rights as a research subject, call the Committee for the Protection of Human Subjects at (713) 500-3985.

Signature of Patient

DATE/TIME

Name of Patient (PLEASE PRINT)

DATE

Signature of Investigator

DATE/TIME