Shaukat Khanum Memorial Cancer Hospital and Research Centre

Consent to Participate in Research

R/CEN/CRO-002/V.2

Phenotype-based Model for Managing Chronic Post-treatment Pain Among Head and Neck Cancer Survivors: A Pilot Study

You are asked to participate in a research study conducted by Dr Khawaja Shehryar Nasir, from the Department of Internal Medicine at Shaukat Khanum Memorial Cancer Hospital and Research Center (SKMCH & RC). The Institutional Review Board (IRB) of SKMCH & RC has reviewed this project. The Institutional Review Board (IRB) of SKMCH & RC has reviewed this project. IRB is an independent hospital committee that safeguards the welfare and rights of human research participants. Your participation in this study is entirely voluntary. If you decide to participate, you will be asked to sign this consent form. Please read the information below and ask questions about anything you do not understand, before deciding whether or not to participate.

A. INFORMATION ON THE RESEARCH

1. Why Are You Being Asked to Take Part in This Research?

We are inviting all patients to participate in this research study who are experiencing pain due to treatment you have received for cancer of the face, jaw, oral cavity or throat.

2. Why Is This Study Being Done?

This study is evaluating the safety and effectiveness of these guidelines in managing cancer treatment-related pain. The information gathered will help plan a larger study in the future.

3. How Many People Will Take Part in The Study?

About 40 patients from SKMCH&RC, Lahore will take part in this study.

4. What Is Involved in The Study?

After written informed consent, you will have three assessments. The first one will be in person. During this visit, you will be asked about your pain and will need to fill out some questionnaires. A pain specialist will examine you and prescribe pain medications or local injections using these guidelines, based on your symptoms and examination. These medications are routinely used for the management of cancerous and non-cancerous pain disorders. However, the protocol for using these medications has been modified.

5. How Long Will You Be in The Study?

The study duration is around 12 months after IRB approval. However, your participation will last for 1 month at the maximum. Each encounter (total of 3) will take not more than 20 minutes (each) of your time.

B. POTENTIAL RISKS AND DISCOMFORTS

You will be receiving medications and/or local injections for cancer treatment-related pain. These modalities are routinely used for the management of cancerous and non-cancerous pain, however, the protocol for using these modalities has been modified. These modalities can cause various side effects. You will receive one or more modalities depending on your signs and symptoms.

The possible common risks associated with the use of medications are blurred vision, change in taste, constipation, depression, diarrhoea, difficulty concentrating, dizziness, drowsiness, dry mouth, erythema of skin, fatigue, fluid retention, gait disturbance, gas or heartburn, headache, hearing loss, lightheadedness, nausea, problems with memory, rash, skin blister, sleepiness, sore throat, stuffy or runny nose, sweating, tiredness, upset stomach or stomach pain, unsteadiness, urinary hesitancy, vomiting, weakness and weight gain.

Injections containing local anaesthetics are associated with a risk of local pain, bruising or swelling; lightheadedness, dizziness, vasovagal reaction, temporary numbness, weakness or paresthesia in distribution of blocked nerve and local infection.

C. POTENTIAL BENEFITS TO SUBJECTS AND/OR TO SOCIETY

Your participation in this study may lead to significant relief from cancer treatment-related pain. Furthermore, your involvement will significantly assist researchers in evaluating the effectiveness of these guidelines in managing cancer treatment-related pain. It could potentially result in better treatment for similar pain conditions in the future by healthcare professionals.

D. ALTERNATIVES TO PARTICIPATION

Your participation is voluntary, and you may choose not to participate. If you decide not to participate in this study, it will not affect the standard of care that you are receiving at Shaukat Khanum Memorial Cancer Hospital and Research Center.

You may feel anxiety or psychological discomfort by participating in this research. If you have such feelings talk to your study team/ share your concerns with your study team. You may also opt not respond to questions you are not comfortable or you may choose to withdraw from participation at any time.

E. CONFIDENTIALITY

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by assigning each participant a unique serial number. Likewise, all questionnaires will be kept in a secure and locked cabinet. The electronic files will be kept on a password-protected computer in a safe, locked office. Only study personnel will have access to data. The information will only be shared between the researchers. The investigator will maintain all study records following the completion or termination of this study in accordance with institutional policy.

F. PAYMENT FOR PARTICIPATION

Participants will not receive any special favors or compensation for participating in this investigation.

G. COMPENSATION/MEDICAL TREATMENT IN CASE OF INJURY

Your participation is entirely voluntary and will not involve any monetary benefits but any adverse event occurring due to participation in research will be managed as per hospital policy.

For more guidance, or to address any of your concerns or queries while being part of this research study at any time we encourage you to contact Secretary, Institutional Review Board at +92-42-35905000 Ext 4280 or mail at crc3@skm.org.pk.

H. PARTICIPATION AND WITHDRAWAL

You can choose whether or not to be in this study. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind or loss of benefits to which you are otherwise entitled. You may also refuse to answer any questions you do not want to answer. There is no penalty if you withdraw from the study and you will not lose any benefits to which you are otherwise entitled. We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

I. IDENTIFICATION OF INVESTIGATORS

If you have any questions or concerns about this research, please contact Dr. Khawaja Shehryar Nasir (Principal Investigator) at 042-35905000 Ext 4052, 4452 or you may email at shehryarnasir@skm.org.pk.

J. RIGHTS OF RESEARCH SUBJECTS

The Institutional Review Board of SKMCH & RC has reviewed this project. If you have any concerns or questions about your rights in this study as a research subject, you should contact the Secretary, Institutional Review Board at +92-42-35905000 Ext 4280 or mail at crc3@skm.org.pk

K. UNDERTAKING OF INFORMED CONSENT

	Yes	No
I voluntarily agree to participate in this research study.	☐	☐
I understand the procedures described above.	☐	☐
All my questions have been answered to my satisfaction.	☐	☐
I have been given a copy of this form.	☐	☐

_____ _____

Name of Subject MRNo. / Participant ID

_____ _____

Signature of Subject Date

_____

Name of Witness (applicable in case participant in unable to read)

_____ _____

Signature of Witness Date

_____

Name of Interpreter (applicable in case of language barrier)

_____ _____

Signature of Interpreter Date

_____

Name of the Person obtaining consent

_____ _____

Signature & Employee code of Person obtaining consent Date

Note: Routing of copies of the consent form:
1) One copy to be given to patient/family;
2) One to be kept in investigator's file/Research record;
3) One to be placed in patient's Medical Record in case of interventional studies