PATIENT INFORMATION AND INFORMED CONSENT

Dear Patient,

After talking with your doctor and reading and understanding the following information, you can decide whether you want to participate in biomedical research. If you choose to participate, you may withdraw your consent from the study without giving a reason at any phase of this study.

NAME OF THE RESEARCH

Effect of vitamin D deficiency on the development of ARDS in a patient after oesophagal resection for carcinoma.

(Effect of vitamin D deficiency on the development of a severe pulmonary complication in the postoperative period after oesophagal surgery for malignancy)

BIOMEDICAL RESEARCH OBJECTIVES

The main aim of our research is to find out whether low vitamin D levels in the patient's body can be the cause of serious postoperative pulmonary complications after oesophagal cancer surgery. The risk of multiple complications in the postoperative period with varying degrees of severity often accompanies oesophagal surgery for malignancy. Most often, pulmonary complications arise, which subsequently prolong the length of hospital stay, impair the healing of surgical wounds, and are frequently the main reason why intensive care doctors cannot wean off the patient from the ventilator. We cannot predict with certainty which patients will develop serious postoperative complications. Some of the risk factors that promote the development of postoperative pulmonary complications include, for example, long-term smoking, chronic obstructive pulmonary disease, chemotherapy, and radiotherapy before surgery. Vitamin D has a crucial role in the human body, not only in bone metabolism but also in fighting infection. The results of blood tests on a large group of people showed that even healthy people now have significantly reduced vitamin D levels. Low vitamin D levels in the blood may also be one of the causes of serious postoperative pulmonary complications.

This study aims to confirm or refute whether preoperative administration of vitamin D reduces the risk of pulmonary complications.

COURSE OF RESEARCH

After signing an informed consent, you will be enrolled in the research. After your admission to the Department of Thoracic Surgery and before your surgery, we will evaluate the vitamin D level in your blood. The test will be done from a blood sample as part of other necessary investigations. You will then be randomly allocated to one of two patient groups. Neither you nor the doctor will know which group you have been assigned to. One group will be given 15 ml (300,000 IU) of vitamin D orally, and the other group will be given 15 ml of MCT oil 3 to 5 days before surgery. Their administration is not risky for you. We will do a follow-up blood sample on the day of surgery and postoperative day 6. On the day of surgery, you will have a catheter inserted under local anaesthetic through a large vessel in

your neck or under your collarbone and a catheter in an artery in your groin area. These two catheters are always inserted in patients undergoing oesophageal resection. Their insertion is not related to your inclusion in the study. The data we obtain from them are fundamental in managing general anaesthesia and intensive care in the early postoperative period. Surgery and other treatments will follow standard procedures for all patients. We will contact you by telephone on the 90th day after surgery to update you on your condition.

RISKS OF THE PROJECT

Your participation in the research involves general risks arising from the surgical procedure and risks associated with inserting catheters before surgery. However, these risks are equally taken by patients not enrolled in the study.

The general risks of surgery include:

- Risks associated with general anaesthesia.

- Risks associated with surgery

- Risks associated with possible local and systemic infectious complications.

- Risks associated with epidural catheter insertion.

RIGHT TO REFUSE OR WITHDRAW

Your participation in biomedical research is voluntary. Allow yourself plenty of time to consent or refuse to participate in the study. You may withdraw from the project at any time without giving a reason. Your withdrawal from the study will not affect your future treatment or your relationship with your physician and other hospital staff.

Authorized persons may have access to your medical records. All information is strictly confidential, and research team members will never reveal your identity. The research team will strictly use your medical records only for this project.

Neither your attending physician nor any other staff involved in the implementation of this project will benefit financially from your participation in the study.

The Local Ethics Committee approved this protocol on September 26, 2018. The mission of the Ethics Committee is to uphold all conditions of patient safety and rights.

CONTACT PERSONS

If you have any problems or questions, please contact Dr. Katarína Tarabová, PhD. (telephone: 02/48234 200, address: Ružinovská 6, 826 06 Bratislava).

INFORMED CONSENT

I agree to participate in the biomedical research entitled: Influence of vitamin D deficiency on the development of ARDS in a patient after oesophagal resection for carcinoma.

I give my voluntary consent to participate in this research, and I have the option to withdraw from this research at any time without giving any reason. Withdrawal will not affect my relationship with my physician. All information about me is strictly confidential. According to Act No. 18/2018 Coll. and 576/2004 Coll.

I have been informed orally and in writing about this research.

The objectives and risks of the research have been explained to me, and I voluntarily consent to participate in this study.

Patient's name.....

Signature.....Date.....

Name of research investigator: Dr. Katarina Tarabova, PhD.

Signature.....Date.....

Name of the supervisor and professional guarantor of the research:
Dr. Miroslav Janík, Assoc. Prof., PhD.

Signature.....Date.....