

DOKUZ EYLUL UNIVERSITY
"NON-INTERVENTIONAL CLINICAL TRIALS"
INFORMED CONSENT FORM FOR

Name of the Study: The Impact of Microbiota and Associated Blood Tryptophan Metabolites on Pain Perception in Patients Undergoing Lumbar Disc Herniation Surgery

Name of the Principal Investigator: Res. Asst. Dr. Yunus ÇELİK

Name of the Co-Investigator: Assoc. Prof. Dr. Hale AKSU ERDOST

You have been invited to take part in the study titled "The Impact of Microbiota and Associated Blood Tryptophan Metabolites on Pain Perception in Patients Undergoing Lumbar Disc Herniation Surgery". This study is conducted for scientific research purposes, and participation is voluntary.

Before you decide whether or not to participate in this research, you need to know why and how the research will be conducted. Therefore, it is of great importance to read and understand this form. If there are things that you do not understand and that are not clear to you, or if you want more information, you can ask the researcher who was given your contact information.

What is the purpose of the research; How many other people besides me will participate in this research?

- *The aim of the study is to investigate the relationship between microbiota and blood tryptophan metabolites (Picolinic Acid, 3-Hydroxykynurene, Anthranilic Acid, Kynurene, Quinolinic Acid, Kynurenic Acid, Xanthurenic Acid) and their impact on acute pain perception..*
- *Microbiota refers to all microorganisms living in the human body. The genome of these microorganisms is called the microbiome. The human microbiota varies widely between individuals. Many factors, from the type of delivery to the stress at birth, the lifelong diet and the antibiotics used, affect and change the human microbiota. We plan to evaluate the extent to which these differences change the perception of pain by comparing them with VAS scores.*
- *It is planned that 37 participants will participate in the study.*

What awaits me if I participate in this research?

Nothing we have already done in routine practice for your surgery will change. Only 2 cc of the blood already routinely taken before the surgery will be used, no additional blood will be taken. No additional intervention will be applied to the routine procedure. The costs of the procedures required for the parameters to be looked at during this study will not be paid to you or to any official or private institution or organization under your guarantee.

Tryptophan metabolites formed as a result of macrobiota in the blood (2 ml) taken from you during your routinely planned examination and treatment procedures due to your disease Picolinic Acid, 3-Hydroxykynurene, Anthranilic Acid, Kynurene, Quinolinic Acid, Kynurenic Acid, Xanthurenic Acid It will be investigated how the level of named substances changes. The relationship between the differences of these substances and the change in your pain will be investigated.

Should I participate in this research?

Taking part in this research is entirely up to you. Even if you sign this form now, you are free to leave the research at any time without giving a reason. If you do not want to participate or leave the study,

the most appropriate treatment plan for you will be applied without being affected by this decision. If the investigator decides that it is not beneficial for you to continue, he or she may exclude you from the research, in which case the most appropriate treatment will be applied to you as standard.

What are the possible risks of the research?

There is no possible risk in our research.

What precautions would be taken to address the possible risks of the research?

All kinds of medical interventions will be made by us in case of any health problems that may arise related to the research; All expenses in this regard will also be covered by us

How much does it cost me to participate in this research?

Taking part in this research is entirely voluntary. You will not be paid anything for this research. Expenses that may occur during the research will not be paid to you and the institution you are affiliated with.

How will my personal information be used?

The researcher conducting the research will use your personal information to conduct the research and statistical analysis, but your identity information will be kept confidential in accordance with medical ethics and KVKK regulations. Your information to be used for research will not be shared with third parties.

Only if necessary, ethics committees or official authorities can review information about you. At the end of the research, you have the right to request information about your own results. The results of the research can be published in the medical literature at the end of the research, but your identity will not be disclosed.

STATEMENT OF THE PARTICIPANT/PATIENT

Dokuz Eylül University, Department of Anesthesiology and Reanimation, Research. Asst. Dr. Yunus ÇELİK stated that a medical research would be carried out, and the above information about this research was conveyed to me and I read the relevant text.

I did not encounter any coercive behavior about my participation in the research. I also know that if I refuse to participate, it will not cause any harm to my medical care and my relationship with my treatment. During the execution of the project, I can withdraw from research without giving any reason. (*However, I am aware that it would be appropriate to inform in advance that I will withdraw from the research in order not to put the researchers in a difficult situation*). I was also informed by the researcher that I could be excluded from the research provided that no harm was done to my medical condition.

I do not assume any monetary responsibility for research expenses. I won't be paid either.

I understand that the confidentiality of personal information about me obtained from the research will be protected.

I was assured that if any health problems that may arise due to the research application arise, all kinds of medical intervention will be provided. (I'm not going to be financially burdened with these medical interventions either).

I have been informed about the research by Res. Asst. Dr. Yunus ÇELİK from Dokuz Eylül University, Department of Anesthesiology and Reanimation.

I understand the details of the research and agree to participate voluntarily. I am aware of my rights to withdraw from the study at any time. No coercive methods have been used to influence my decision. I understand that my confidentiality will be protected, and any potential health issues related to the research will be addressed without financial burden to me.

I have understood in detail all the explanations that have been given to me. Under these conditions, I agree to participate in the clinical trial voluntarily, without any pressure or coercion.

A copy of this signed form paper will be given to me.

Participant

Name, surname:

Address:

Wire:

Signature:

History:

Interview witness

Name, surname:

Address:

Wire:

Signature:

History:

Researcher interviewing the participant

Name, surname, title:

Address:

Wire:

Signature:

History: