# Title: Comparison of Bolus and Continuous Hydration Regimens for the Prevention of Contrast-Associated Acute Kidney Injury in the Emergency Department: A Randomized Controlled Non-Inferiority Trial

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# INFORMED CONSENT FORM

Name of Research Project: Comparison of Bolus and Continuous Hydration Regimens for the Prevention of Contrast-Associated Acute Kidney Injury in the Emergency Department: A Randomized Controlled Non-Inferiority Trial

Name of Responsible Investigator: Mustafa Çalık
Names of Other Investigators: Yunus Emre Gemici, Furkan Ay, Alper Görkem Çimen

You are invited to participate in a study titled "Comparison of Bolus and Continuous Hydration Regimens for the Prevention of Contrast-Associated Acute Kidney Injury in the Emergency Department: A Randomized Controlled Non-Inferiority Trial". The reason you were invited to participate in this study is that you were found to have a high likelihood of developing contrast nephropathy. This study is being conducted for research purposes and participation is based on voluntary consent. We would like to inform you about the research before you decide whether to participate in the study. After you have been fully informed about the study and your questions have been answered, you will be asked to sign this form if you wish to participate. This research is under the responsibility of Associate Professor Dr. Mustafa Çalık at the Emergency Medicine Clinic.

What is the purpose of the study; how many other people beside me will participate in this study?

The aim of this study is to develop treatment methods to prevent contrast-induced nephropathy in patients with high kidney values who undergo contrast-enhanced (with medication) tomography in the emergency department. Contrast agents are nephrotoxic substances (which can cause kidney damage) used in contrast-enhanced CT scans. This damage is more common in patients with kidney values above normal. The proven treatment method to prevent this damage is fluid therapy. This treatment involves administering fluids intravenously

before and after the contrast agent is given. In this study, protective fluid treatment regimens will be compared.

266 participants will be included in the study. The study will be conducted at a single center in the emergency department of Gaziosmanpaşa TREH.

Should I participate in this study?

Whether or not you participate in this study is entirely up to you. Even if you sign this form now, you are free to quit your job at any time without giving a reason. If you do not wish to participate or leave the study, the most appropriate treatment plan for you will be implemented by your doctor. Similarly, the doctor conducting the study may decide that continuing the study would not be beneficial for you and may exclude you from the study. In this case, the most appropriate treatment for you will be selected.

What can I expect if I participate in this study?

Patients with kidney values above the normal range who require a contrast CT scan in the emergency room are planned to be divided into two groups and receive the same amount of intravenous fluid treatment at two different speeds. One person in this group is receiving 2.5 hours of fluid therapy, while the other is receiving 10 hours of fluid therapy. The total amount of fluid therapy received does not differ between the groups. Patients will be randomly assigned to these groups. If patients are discharged, they need to be called back for a check-up 72 hours later and provide blood again for kidney values. If there is a significant increase in these values, consultation will be sought regarding admission to the relevant department. If there is no increase (damage) in kidney values, the patient will be informed. The research will be conducted for a period of 1 year.

Patients will have 4 ml of blood drawn twice for research purposes: once upon emergency room admission and again when they come for a follow-up visit 72 hours later. The blood samples taken will

be examined for urea and creatinine values, which indicate kidney function, and for changes in these values.

Are there any risks or discomforts associated with the study?

The treatment applied in our study is the one whose benefit has been proven in research and is recommended for routine application. The application of this treatment at different speeds and durations will be compared.

1. Fluid therapy in patients with advanced heart failure can cause strain on the heart. Patients presenting with complaints related to heart failure will not be included in the study. Fluid therapy will be administered at half dose to heart failure patients who have no complaints regarding this.

2. Any potential harm you may experience due to the research will be addressed by us thru all necessary medical interventions; all expenses related to this will also be covered by us.

What are the benefits of my participation in the study?

By participating in this study, you will contribute to the development of treatment aimed at protecting patients at risk due to high kidney values requiring contrast-enhanced CT scans in the emergency department. This contribution will ensure the scientific development of treatments and prevent more people from receiving the correct and effective treatment. This situation will positively impact public health.

What is the cost of participating in this study?

By participating in the study, you will not incur any financial burden, nor will you receive any payment.

How will my personal information be used?

Your occupational physician will use your personal information to conduct research and statistical analysis, but your identity will be kept confidential. Only if necessary, information about you may be

reviewed by ethics committees or official authorities. At the end of the study, you have the right to request information about your own results. The study results can be published in the medical literature upon completion of the study, but your identity will not be disclosed.

Who can I contact for more information?

Please contact the following person if you require additional information regarding the study.

Dr. Yunus Emre Gemici POSITION: Emergency Medicine Resident Doctor PHONE: 0542 546 10 70

(Participant/Patient Statement)

I was informed by Dr. …… that a medical research study would be conducted in the Emergency Medicine Clinic, and the above information regarding this study was conveyed to me. I have read the relevant text. After this information, I was invited to participate in such a study.

I haven't encountered any coercive behavior regarding my participation in the research. I also know that if I refuse to participate, this will not harm my medical care or my relationship with my doctor. I can withdraw from the study at any time during the project's execution without giving any reason. (However, I am aware that it would be appropriate for me to inform you in advance that I will withdraw from the study so as not to put the researchers in a difficult position). I can also be excluded from the study by the researcher, provided my medical condition is not harmed.

I am not incurring any financial responsibility for the expenses related to the research. I will not be paid either.

I understand that the confidentiality of my personal information obtained from this research will be protected.

I was given the necessary assurance that any health problems that may arise due to the research application will be provided with all kinds of medical intervention. (I will also not incur any financial burden related to these medical interventions).

I understand that if I encounter a health issue during the research, I can call Dr. Yunus Emre Gemici at any time at 0542 546 10 70, Karayolları mah. Osmanbey cad. 621 sk. Gaziosmanpaşa/İSTANBUL.

I have understood all the explanations given to me in detail. Under these conditions, I agree to participate in the clinical trial in question of my own free will, without any pressure or coercion, and voluntarily.

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

Participant Name, Surname:
Address:
Tel:
Signature:
Date:

Physician who interviewed the participant Name, title:
Address:
Tel:
Signature:
Date: