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INFORMED CONSENT FORM (INF)

Dear Volunteer,

conducted by Gamze Ataman Yıldız titled "Evaluation of the Effect of **Prehabilitation on Patient Outcomes in Frail Patients Undergoing Elective Coronary Artery Bypass Graft** . " **Before agreeing to participate in this study, you must fully understand the purpose of the study and be free to make your decision after being fully informed about the research .**

This information form has been prepared specifically for you to provide a detailed overview of the study. Please read it carefully. If you find any points about the study that you do not understand or that are not addressed in this form, please contact your physician and ask for clear answers.

Participation in this study is entirely **voluntary** . You have the right not to participate in the study or to withdraw from the study at any time. After you have been fully informed about the study, your physician will give you time to freely consider your decision before signing the form. Regardless of your decision, your physicians will continue to fulfill their responsibilities to ensure and maintain your optimal health. Do not be pressured or pressured into participating in this study. Sign the form only if you agree to participate.

1. Name of the study: Investigation of the Effect of Prehabilitation on Patient Outcomes in Frail Patients Planned for Elective Coronary Artery Bypass Graft

2. Names, institutions and contact numbers of researchers:

Gamze ATAMAN YILDIZ
SBÜ İstanbul Mehmet Akif Ersoy
GKDC EAH
Tel: 0 542 775 17 80

Research purpose : To determine the effect of prehabilitation care on patient outcomes.

3. Number of volunteers

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The total number of volunteers expected to take part in this research is at least 100.

4. Duration of participation in the study

The time period for which you will be included in this study includes the period of approximately 3-4 weeks before the surgery when you are invited for a preliminary interview, the time you stay in the hospital after the surgery, and the 30-day period after you are discharged.

5. Treatments to be applied in the study

In the study, volunteers will not be administered any medication or procedure other than the hospital routine.

6. The probability of random assignment of volunteers to study groups for different treatments, if any

There will be two groups in the study.

7. Research method

This randomized controlled study will be conducted with a preoperative patient information form, mini mental frailty scale, mini nutritional scale and 6-minute walk test, comorbidity classification and Borg scale. Postoperative patient information form, activities of daily living scale, 6-minute walk test, Borg scale, mini nutritional test and postoperative recovery index and Clavien scale. dindo classification will be applied.

8. Material to be collected from volunteers

No materials will be taken from volunteers.

9. Conditions for participating in the study - Why was I selected?

To be included in this study, you must meet the following conditions:

- Agreeing to participate in the research,
- Undergoing elective open coronary artery bypass grafting
- Being 60 years old or older,
- Being in the frail patient status as a result of the FRIED Frailty Scale,
- Being able to communicate in Turkish.

10. Do I have to participate in the study/continue to participate until the end once I have participated?

Whether or not you participate in this study is entirely up to you. Even if you sign this form now, you are free to withdraw from the study at any time without giving a reason.

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If you decide not to participate or withdraw from the study, your healthcare team will continue to implement the most appropriate treatment and care plan for you.

11. Volunteer responsibilities: None

12. What will happen to me if I agree to participate?

In this research, only the questionnaire will be applied to you.

13. What are the possible disadvantages and risks of participating in research?

There are no disadvantages or risks to participating in this study.

14. What are the possible benefits of participating in research?

As a result of participating in the study, your improved post-operative recovery will be evaluated.

15. What if something goes wrong with the research?

There are no risks associated with the study. There is no compensation. However, you can contact the researchers 24/7 at the provided mobile phone number for more information.

16. Liability/responsibility in case of any damage that may arise from the research

If you suffer any harm as a result of the research, the costs of treatment will be covered by you.

17. Information on compensation to be given to the volunteer or treatments to be provided, if required by relevant legislation, and payments for expenses such as transportation and meals to be made to the volunteers, if any.

There is no compensation, expense or payment.

18. How will research expenses be covered?

You or your social security institution will not be charged for anything performed voluntarily for "research purposes." You will not be charged for participation in this research or for any expenses that may arise from it. Any additional tests, physical examinations, or other research expenses in addition to those required for your condition will not be covered by you or any public or private institution under your insurance.

19. Conditions for exclusion from the study

- You do not fulfill the requirements of the applied treatment plan,
- You disrupt the research program,

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- The researcher may remove you from the study without your consent, for reasons such as if you are exposed to an undesirable effect that may develop due to or independent of the study.

This will not cause any change in your treatment.

However, even if you are excluded from the study, medical data about you may be used for scientific purposes.

20. Refusal to participate in the study and withdrawal status

Participating in this study is entirely at your discretion.

You may refuse to participate in the study or withdraw from the study at any stage; if you decline to participate or withdraw after participation, your decision will not affect your treatment. Even if you withdraw from the study or are removed by the researcher, your medical data may be used for scientific purposes.

21. Sharing new information and stopping research

While the study is ongoing, any new medical information and results, whether positive or negative, will be communicated to you or your legal representative as soon as possible. These results may affect your desire to continue the study. In this case, you may request that the study be stopped until you make a decision.

22. What are the alternative diagnostic and treatment methods in therapeutic research?

It is not a therapeutic research.

23. How will the confidentiality of my identity and the data obtained be ensured?

Your researcher will use your personal information to conduct the study and statistical analyses, but your identity will be kept confidential. Ethics committees or official authorities may review your information only if necessary. At the end of the study, you have the right to request information about your findings. The study results may be published in the medical literature upon completion, but your identity will not be disclosed.

24. Will I be informed at the end of the research?

At the end of the study, researchers will first inform volunteers about the results. If possible, you will receive a copy of the results and publications.

25. Who should I call for complaints, questions, and more detailed information regarding my rights as a volunteer?

This research has been approved by the Clinical Research Ethics Committee of Istanbul Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and Research Hospital. If you have any complaints regarding your participation in the research, you

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can contact the committee through the Ethics Committee Member/Chair/Vice Chair Abdurrahman Eksik (0212 692 20 00/4009). All complaints will be treated confidentially, investigated, and you will be informed of the outcome.

About your rights and the harms you may encounter in connection with the research;

Contact person : Gamze ATAMAN YILDIZ

Institution : Istanbul Mehmet Akif Ersoy Thoracic and Cardiovascular
Surgery Training and Research Hospital

Address : İstasyon Neighborhood, Turgut Özal Boulevard, No:11,
Küçükçekmece, Istanbul

Phone number : 0542 775 17 80

26. Institution supporting the research

There is no institution supporting the research.

27. Ethics Committee approval

Working in Istanbul Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery was approved by the Ethics Committee of the EAH.

28. Thank you for participating in the study.

CONSENT TO PARTICIPATE IN THE RESEARCH

I have read and listened to the six (6) pages of text above, which outline the information that must be provided to the subject before the study begins. I have asked the researcher all questions that may come to mind, and I fully understand all written and verbal explanations given to me. I have been given sufficient time to decide whether I wish to participate in the study. Under these circumstances, I authorize the researcher to review, transfer, and process my medical information, and I accept the invitation to participate in this study with full participation, without any coercion or pressure. I understand that my participation in the study is voluntary and that I may withdraw from the study at any time, with or without justification. I understand that by signing this form, I will not lose any rights granted to me by law. I have been given a signed and dated copy of this form.

Voluntarily		Signature
Name - Surname		
History		

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Turkish Republic
Ministry of Health
SBU. Istanbul Mehmet Akif Ersoy
Thoracic, Cardiovascular and Vascular Surgery Training and Research Hospital
Clinical Research Ethics Committee



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Guardian (If applicable)		Signature
Name - Surname		
History		
Researcher		Signature
Name - Surname		
History		
The Person Who Witnesses the Consent Process from Beginning to End		Signature
Name - Surname		
History		

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