

INFORMED VOLUNTARY CONSENT FORM

Official Title: Comparison of Bidirectional Palpation Test and
Transit Time Flow Measurement for LIMA–LAD Graft Patency

NCT Number: NCT06934993

Date: 11.10.2024

Sponsor Institution: Istanbul University–Cerrahpaşa, Faculty
of Medicine, Department of Cardiovascular Surgery

Ethics Approval: Approved by the Istanbul University–
Cerrahpaşa Clinical Research Ethics Committee (approval
dated 11.10.2024; Turkish document added to the end of the
file)

INFORMED VOLUNTARY CONSENT FORM

You are invited to participate in a research study conducted by Dr. A. Orhun YENİĞÜN titled **“Comparison of LIMA-LAD Graft Patency With Bidirectional Palpation Test, Transit Time Flowmeter (TTFM), and Coronary CT Angiography.”** This research is planned as a retrospective–prospective (hybrid) cohort study. This consent form has been prepared to inform patients who will participate in the study prospectively (i.e., going forward in time) and to obtain their consent.

The aim of this study is to evaluate the left internal mammary artery (LIMA), which is the most important and long-lasting graft used in coronary artery bypass surgery. It is planned to include 80 patients who have undergone coronary artery bypass grafting (CABG). The study is expected to be completed in approximately 2 months after reaching the target number of participants.

Participation in this study is entirely voluntary. In this study, the patency (openness) of the LIMA–LAD anastomosis, which is routinely used during your CABG surgery, will be assessed. The correlation between graft flow measurements using a flowmeter and the bidirectional palpation test—both of which are routinely used during surgery and do not pose additional surgical risk—will be evaluated. These intraoperative data will be compared with early postoperative contrast-enhanced coronary computed tomography angiography (CTA) results.

In order to contribute to the goals of this study, you will be asked to undergo a contrast-enhanced coronary CTA at our university hospital in the early postoperative period, and the appointment will be arranged by us. This imaging is non-invasive, though contrast material will be administered during the procedure. Possible side effects include allergic reactions to the contrast agent and contrast-induced nephropathy. The CTA will also assess graft patency, sternal healing, and lung parenchyma status.

By reading and signing this form, you confirm that you agree to participate in the study. However, you have the right to refuse participation or to withdraw from the study at any time without giving a reason.

The data collected in this study will be used solely for research purposes, and your personal information will be kept confidential. However, your anonymized data may be used for publication purposes. Your contact information may be transferred to a “shared participant pool” only with your permission, to allow other researchers to contact you.

If you require additional information now or later beyond what has been provided about the study, you may ask the researcher or contact them via email at orhunyenigun@iuc.edu.tr or phone at **0534 621 4600**. If you would like to be informed about the overall or individual results after the study is completed, please notify the researcher.

I have read the information provided above, which is required to be given to participants prior to the study. I understand the scope and purpose of the study, as well as the responsibilities I am voluntarily assuming. The study was explained to me in writing and verbally by the researcher(s) named below. I was also verbally informed about the potential risks and benefits. I was assured that my personal data will be protected with due care.

Under these conditions, I voluntarily agree to participate in this study without any pressure or coercion.

Ethics Committee Approval (English Translation)

Participant

Full Name:

Signature:

Contact Information:

E-mail:

Phone:

☐ I agree

☐ I do not agree

(for the transfer of my contact information to the “shared research pool” so that other researchers may contact me – please check the appropriate box)

For Minors or Legally Incapacitated Individuals Guardian or Legal

Representative

Full Name:

Signature:

Researcher

Full Name:

Signature:

Witness

Full Name:

Signature:

Ethics Committee Approval (English Translation)

REPUBLIC OF TURKIYE

ISTANBUL UNIVERSITY-CERRAHPASA

RECTORATE

Clinical Research Ethics Committee

Ref No: E-83045809-604.01-1014609 Date:

12.06.2024

Subject: Research Assistant Dr. Abdullah Orhun YENIGUN Ethics

Committee Decision

To: Department of Cardiovascular Surgery Chairmanship

Reference: Your letter dated 11.10.2024, numbered 806763

Upon review of the study titled "Comparison of LIMA-LAD Graft Patency via Bidirectional Palpation Test, Transit Time Flow Meter (TTFM), and Coronary CT Angiography", to be conducted under the supervision of Research Assistant Dr. Abdullah Orhun YENIGUN, with the consultancy of Lecturer Dr. Cigdem Tel USTUNISIK and Prof. Dr. Suat Nail OMEROGLU, from your department, the project was discussed in our ethics committee meeting dated 11.06.2024 and was deemed ethically appropriate.

Kindly be informed.

Prof. Dr. Mehmet Sarper ERDOGAN Chairman

Ethics Committee Approval (English Translation)

Attachment: 1 hard copy of the decision will be delivered in person.

This document has been signed with a secure electronic signature.

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REKTÖRLÜĞÜ
Klinik Araştırmalar Etik Kurulu



Sayı : E-83045809-604.01-1014609
Konu : Araş.Gör.Dr.Abdullah Orhun YENİĞÜN
etik kurul kararı

12.06.2024

KALP VE DAMAR CERRAHİSİ ANABİLİM DALI
BAŞKANLIĞINA

İlgi : 11.10.2024 tarihli 806763 sayılı yazınıza istinaden

Anabilim Dalınızda görevli Araş.Gör.Dr.Abdullah Orhun YENİĞÜN'ün yürütücülüğünde, Öğr.Gör.Dr.Çiğdem Tel ÜSTÜNİŞİK, Prof.Dr.Suat Nail ÖMEROĞLU'nun danışmanlığında yapılacak olan "LIMA-LAD Greft Açıklığının Çift Yönlü Palpasyon Testi, Transit Time Flow Meter (TTFM) ve Koroner BT Anjiyografi İle Karşılaştırılması" başlıklı çalışma 11.06.2024 tarihli etik kurulumuzca müzakere edilmiş olup, etik açıdan uygun görülmüştür
Bilgilerinize rica ederim

Prof. Dr. Mehmet Sarper ERDOĞAN
Başkan

Ek:01 Adet karar fiziki olarak teslim alınacaktır

Bu belge, güvenli elektronik imza ile imzalanmıştır.

Belge Doğrulama Kodu :BSRST3H8V2

Belge Takip Adresi : <https://www.turkiye.gov.tr/istanbul-universitesi-cerrahpasa-ebys>

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