

Time for a Diagnostic Paradigm Shift From
STEMI/NSTEMI to OMI/NOMI
(DIFOCCULT-3)

NCT06570759
June 29th, 2024

Kimlik Bilgileri (Identification)

Study ID#

National ID#

Has the patient been excluded ?

- ☐ Evet
☐ Hayır

The reason for exclusion

- ☐ An alternative cause for troponin elevation
☐ Pregnancy or suspicion of pregnancy
☐ Reperused by thrombolytic therapy instead of PCI
☐ Rejection or withdrawal of consent
☐ Unable to retrieve pre-PCI ECGs
☐ Other

If other is chosen, please explain.
(Please briefly explain the reason for exclusion.)

Name and surname

(e.g.; John Doe)

Age

Gender

- ☐ Male ☐ Female

Boy
(in centimeters)

Kilo
(in kilograms)

Phone number
(Required for follow-up. E.g.; 0532 510 97 98, 0216 283 38 38)

Second phone number (if possible)
(Recommended for follow-up. E.g.; 0532 510 97 98, 0216 283 38 38)

Randomizasyon (Randomization)

Study ID#

Center

- ☐ Ankara Etlik City Hospital
☐ Antalya City Hospital
☐ Bagcilar Training and Research Hospital
☐ Basaksehir Pine and Sakura City Hospital
☐ Dr. Siyami Ersek Thoracic and Cardiovascular Surgery Training and Research Hospital
☐ Erzurum Ataturk University, Faculty of Medicine
☐ Eskisehir Osmangazi University
☐ Eskisehir City Hospital
☐ Kartal Kosuyolu High Specialization Education and Research Hospital
☐ Kütahya Health Sciences University
☐ Marmara University, Pendik Training and Research Hospital
☐ Mehmet Akif Ersoy Training and Research Hospital
☐ Mugla Sitki Kocman University
☐ Necmettin Erbakan Meram Faculty of Medicine
☐ Sirmak State Hospital
☐ Tokat Gaziosmanpasa University Hospital
☐ Van Training and Research Hospital
☐ Van Yuzuncu Yil Faculty of Medicine

Randomization date
(Enrollment date)

Study arm
(According to the team on duty)

- ☐ STEMI/NSTEMI ☐ OMI/NOMI

Ön tanı

(Working diagnosis that caused to proceed to angiography or admission [whichever is the first]. The discharge diagnosis may not be necessarily with the preliminary diagnosis.)

- ☐ ST-segment elevation MI (STEMI) ☐ non-ST-segment elevation MI (NSTEMI) ☐ Other

Any "very-high risk" NSTEMI feature ?

- ☐ Hemodynamic instability or cardiogenic shock
☐ Acute heart failure due to ischemia
☐ Life-threatening ventricular arrhythmias or cardiac arrest
☐ Mechanical complications (ischemic VSD, acute ischemic mitral regurgitation etc.)
☐ Refractory or recurrent chest pain despite medical therapy
☐ Dynamic ST-T wave changes, especially with intermittent ST-segment elevation
☐ None of above

Ön tanı

(Working diagnosis that caused to proceed to angiography or admission [whichever is the first]. The discharge diagnosis may not be necessarily with the preliminary diagnosis.)

☐ Occlusion MI (OMI) ☐ Non-occlusion MI (NOMI) ☐ Other

Any "high risk" feature NOMI ?

- ☐ Hemodynamic instability or cardiogenic shock
- ☐ Acute heart failure due to ischemia
- ☐ Life-threatening ventricular arrhythmias or cardiac arrest
- ☐ Mechanical complications (ischemic VSD, acute ischemic mitral regurgitation etc.)
- ☐ None of above

Please explain

(Unstable angina, suspicious but nondiagnostic ECG, cat lab availability, pre-planned angiography etc.)

Informed consent form

(Downloadable from this link, if required.)

[Attachment: "Onam.pdf"]

Upload the signed informed consent.

(Only signature page is required. Keep the original.)

Since the patient is excluded, you do not need to fill this form.

(If you think this is an error, please check your answer for "Has the patient been excluded ?" on the first form (Identification).)

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Özgeçmiş (Medical History)

Study ID#

Hypertension

(Average blood pressure >140/90 mmHg or use of antihypertensive medication)

☐ Evet ☐ Hayır

Diabetes

(FPG>126 mg/dL for two times or HbA1c>%6.5 or use of antidiabetic medication)

☐ Evet ☐ Hayır

Dyslipidemia

(LDL>160 mg/dL or use of antihyperlipidemic drug)

☐ Evet ☐ Hayır

Active smoking

(Smoking history in the last one year)

☐ Evet ☐ Hayır

Chronic kidney disease

(GFR < 60 ml/min/1.73 m² known or supposed to be longer than 3 months)

☐ Evet ☐ Hayır

Prior myocardial infarct

(Documented diagnosis or imaging evidence of an old [>1 month] myocardial infarct)

☐ Evet ☐ Hayır

Prior percutaneous coronary intervention

(Documented history or imaging evidence of a prior coronary intervention)

☐ Evet ☐ Hayır

Prior coronary arterial by-pass grafting

(Documented history or imaging evidence of a prior CABG)

☐ Evet ☐ Hayır

Since the patient is excluded, you do not need to fill this form.

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Study ID#

Center

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☐ Kütahya Health Sciences University
☐ Marmara University, Pendik Training and Research Hospital
☐ Mehmet Akif Ersoy Training and Research Hospital
☐ Mugla Sitki Kocman University
☐ Necmettin Erbakan Meram Faculty of Medicine
☐ Ordu State Hospital
☐ Sanliurfa Mehmet Akif Inan Training and Research Hospital
☐ Sirnak State Hospital
☐ Tokat Gazi Osman Pasa University Hospital
☐ Umraniye Training and Research Hospital
☐ Van Training and Research Hospital
☐ Van Yuzuncu Yil Faculty of Medicine

Randomization date
(Enrollment date)

Study arm
(According to the team on duty)

- ☐ STEMI/NSTEMI ☐ OMI/NOMI

Preliminary diagnosis
(Working diagnosis that caused to proceed to angiography or admission [whichever is the first])

ST-segment Elevation Myocardial Infarction (MI) Criteria:

(1) New J-point elevation according to the following cut-offs in two consecutive leads:

* In V2-V3, ≥ 40 males ≥ 2 mm; < 40 males ≥ 2.5 mm, females ≥ 1.5 mm,

* in all other leads ≥ 1 mm

* (includes V7-9 ST-segment elevation or V1-4 ST-segment depression for "posterior" MI)

(2) a peak troponin exceeding 99.percentile with a characteristic increase and decrease (retrospective)

(3) a clinical picture compatible with acute coronary syndrome.

STEMI should be selected if proceeded to cath lab only with 1st and 3rd criteria, even if the 2nd criterion is not met (retrospectively). Patients meeting only 2nd and 3rd criteria should be classified as non-ST-elevation myocardial infarction.

☐ ST-segment elevation MI (STEMI) ☐ non-ST-segment elevation MI (NSTEMI) ☐ Other

Any "very-high risk" NSTEMI feature ?

- ☐ Hemodynamic instability or cardiogenic shock
- ☐ Acute heart failure due to ischemia
- ☐ Life-threatening ventricular arrhythmias or cardiac arrest
- ☐ Mechanical complications (ischemic VSD, acute ischemic mitral regurgitation etc.)
- ☐ Refractory or recurrent chest pain despite medical therapy
- ☐ Dynamic ST-T wave changes, especially with intermittent ST-segment elevation
- ☐ None of above

Preliminary diagnosis

(Working diagnosis that caused to proceed to angiography or admission [whichever is the first])

Kriterler:

- (1) ECG findings suggestive of acute coronary occlusion (or an OMI diagnosis by the App)
- (2) a peak troponin exceeding 99.percentile with a characteristic increase and decrease (retrospective)
- (3) a clinical picture compatible with acute coronary syndrome.

OMI should be selected if proceeded to cath lab only with 1st and 3rd criteria, even if the 2nd criterion is not met (retrospectively). Patients meeting only 2nd and 3rd criteria should be classified as NOMI.

☐ Occlusion MI (OMI) ☐ Non-occlusion MI (NOMI) ☐ Other

Any "high risk" feature NOMI ?

- ☐ Hemodynamic instability or cardiogenic shock
- ☐ Acute heart failure due to ischemia
- ☐ Life-threatening ventricular arrhythmias or cardiac arrest
- ☐ Mechanical complications (ischemic VSD, acute ischemic mitral regurgitation etc.)
- ☐ None of above

Please explain

(Suspicious but nondiagnostic ECG, cat lab availability, pre-planned angiography etc.)

Informed consent form

(Downloadable from this link, if required.)

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Upload the signed informed consent.

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Önceki tedavisi (Prior medication)

Study ID# _____

Aspirin
(Medications used before the admission)

☐ Evet ☐ Hayır

P2Y12 inhibitor
(Medications used before the admission)

☐ None
☐ Clopidogrel
☐ Ticagrelor
☐ Prasugrel

OAC/NOAC
(Medications used before the admission)

☐ Evet ☐ Hayır

ACEi/ARB
(Medications used before the admission)

☐ Evet ☐ Hayır

ARNI
(Medications used before the admission)

☐ Evet ☐ Hayır

SGLT2i
(Medications used before the admission)

☐ Evet ☐ Hayır

Beta-blocker
(Medications used before the admission)

☐ Evet ☐ Hayır

Calcium channel blocker
(Medications used before the admission)

☐ Evet ☐ Hayır

MRA
(Medications used before the admission)

☐ Evet ☐ Hayır

Loop diuretic
(Medications used before the admission)

☐ Evet ☐ Hayır

Statin
(Medications used before the admission)

☐ Evet ☐ Hayır

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(If you think this is an error, please check your answer for "Has the patient been excluded ?" on the first form (Identification).)

Başvuru sırasındaki klinik değişkenler (Clinical parameters on admission)

Study ID#

Mode of admission
(Directly or by referral)

- ☐ Directly (by themselves or by ambulance)
☐ Referred (from another institution)

NOTE: With regard to the admission to the randomizing
(PCI-capable) center.

Systolic blood pressure on admission
(in mmHg)

Heart rate on admission
(in beats per minute)

Killip class on admission

NOT: Başvurudan randomizasyonun yapıldığı hastane (ana çalışmacının çalıştığı primer PKG merkezi)
kastedilmektedir.

- ☐ Class 1: No evidence of heart failure
☐ Class 2: Pulmonary rales, S3 or increased jugular venous pressure
☐ Class 3: Overt pulmonary edema
☐ Class 4: Signs of cardiogenic shock (oliguria, cyanosis, pale and clammy skin) or hypotension (SBP < 90 mmHg)

Cardiopulmonary resuscitation before admission
(Need for chest compressions, defibrillation or
intubation before randomization)

- ☐ Evet ☐ Hayır

Creatinine on admission
(Just before or after randomization, in mg/dL, e.g.;
1.2)

Hemoglobin on admission
(Just before or after randomization, in g/dL, e.g.;
12.3)

Very-high troponin level for this center is 1000 ng/L
(According to the kit used by this center in ng/L [=pg/mL]. This level suggests a major epicardial coronary artery
occlusion)

Very-high troponin level for this center is 2400 ng/L
(According to the kit used by this center in ng/L [=pg/mL]. This level suggests a major epicardial coronary artery
occlusion)

Very-high troponin level for this center is 5000 ng/L
(According to the kit used by this center in ng/L [=pg/mL]. This level suggests a major epicardial coronary artery
occlusion)

Troponin on admission
(first troponin in ng/L [=pg/mL], e.g.; 12)

NOTE: If not taken on admission, can be obtained during angiography.

If present, second troponin
(second troponin in the ER in ng/L [=pg/mL], e.g.; 12)

Duration of pain
(The duration of the last pain in minutes. If continuing, calculate the time to ECG from the onset of last constant pain.)

Intermittent chest pain before MI ?
(Before the last infarct-related pain, did the patient experience pain episodes in the previous month ?)

☐ Evet ☐ Hayır

Upload the first ECG
(This may not be the diagnostic one. To upload further ECGs, use additional areas below)

NOTE: Use image files (.jpg, .png, .tiff vb.) or pdf.

or

You can also use report code on PMCardio App
(For example, enter only 6c40a7ab for "Report 6c40a7ab" on PMCardio App.)

{ekg1_reportno}

*must provide a value.

Time of the first ECG
(The date on ECG as day/month/year and hour:minute)

Upload the second ECG
NOTE: Use image files (.jpg, .png, .tiff vb.) or pdf.

or

You can also use report code on PMCardio App
(For example, enter only 6c40a7ab for "Report 6c40a7ab" on PMCardio App.)

{ekg_reportno_2}

*must provide a value.

Upload the third ECG

NOTE: Use image files (.jpg, .png, .tiff vb.) or pdf.

or

You can also use report code on PMCardio App
(For example, enter only 6c40a7ab for "Report
6c40a7ab" on PMCardio App.)

{ekg_reportno_3}

*must provide a value.

Upload the fourth ECG

NOTE: Use image files (.jpg, .png, .tiff vb.) or pdf.

or

You can also use report code on PMCardio App
(For example, enter only 6c40a7ab for "Report
6c40a7ab" on PMCardio App.)

{ekg_reportno_4}

*must provide a value.

Upload the fifth ECG

NOTE: Use image files (.jpg, .png, .tiff vb.) or pdf.

or

You can also use report code on PMCardio App
(For example, enter only 6c40a7ab for "Report
6c40a7ab" on PMCardio App.)

{ekg_reportno_5}

*must provide a value.

Which one of the uploaded ECGs lead to the diagnosis ?
(Enter the number of the diagnostic ECG. If diagnosis
was not based on ECG, enter "0")

Enter the time of this diagnostic ECG
(Enter the time on the diagnostic ECG as
day/month/year and hour:minute. This may be the same
as the first ECG)

Was chest pain present during this diagnostic ECG (or during any of the ECGs, if none of them were diagnostic) ?

☐ Evet ☐ Hayır

How many minutes is it since the last pain stopped ?

(Enter the duration of pain from the cessation of the last episode to the ECG, in minutes.)

Since the patient is excluded, you do not need to fill this form.

(If you think this is an error, please check your answer for "Has the patient been excluded ?" on the first form (Identification).)

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EKG modülü (ECG module) Audit

Study ID#

You are viewing ECGs from the patient with the record number of [record_id], who is a [age] year-old [gender]. This patient was admitted to [merkez] on [randomizasyon_tarihi].

To access PMCardio App: <https://difoccult.pmcario.com>

The first pre-PCI ECG

[ekg1:inline] QoH interpretation:

{ecgmodule_pre1qoh}

The second pre-PCI ECG

[ekg1:inline] QoH interpretation:

{ecgmodule_pre2qoh}

The third pre-PCI ECG

[ekg1:inline] QoH interpretation:

{ecgmodule_pre3qoh}

The fourth pre-PCI ECG

[ekg1:inline] QoH interpretation:

{ecgmodule_pre4qoh}

The fifth pre-PCI ECG

[ekg1:inline] QoH interpretation:

{ecgmodule_pre5qoh}

EKG modülü (ECG module) 1

Study ID# _____

You are viewing ECGs from the patient with the record number of [record_id], who is a [age] year-old [gender]. This patient was admitted to [merkez] on [randomizasyon_tarihi].

To access PMCardio App: <https://difoccult.pmcario.com>

The first pre-PCI ECG

[ekg1:inline]

Expert interpretation:

☐ OMI ☐ not-OMI ☐ Undefined

The second pre-PCI ECG

[ekg2:inline]

Expert interpretation:

☐ OMI ☐ not-OMI ☐ Undefined

The third pre-PCI ECG

[ekg3:inline]

Expert interpretation:

☐ OMI ☐ not-OMI ☐ Undefined

The fourth pre-PCI ECG

[ekg4:inline]

Expert interpretation:

☐ OMI ☐ not-OMI ☐ Undefined

The fifth pre-PCI ECG

[ekg5:inline]

Expert interpretation:

☐ OMI ☐ not-OMI ☐ Undefined

Are there any dynamic changes suggestive of OMI in pre-PCI ECGs ?

☐ Yes
☐ No
☐ Undefined

(Dynamic ST-T changes, Q wave development)

The first post-PCI ECG

[postpci_ekg:inline]

Post-PCI 24h ECG

[postekg24:inline]

Post-PCI 48h ECG

[postekg48:inline]

Post-PCI 72h ECG

[postekg72:inline]

Does ECG show evolution compatible with acute myocardial infarction ?

- ☐ Yes
☐ No
☐ Undefined

(Characteristic Q wave and/or ST normalization and/or T wave inversion)

EKG modülü (ECG module) 2

Study ID# _____

You are viewing ECGs from the patient with the record number of [record_id], who is a [age] year-old [gender]. This patient was admitted to [merkez] on [randomizasyon_tarihi].

To access PMCardio App: <https://difoccult.pmcario.com>

The first pre-PCI ECG

[ekg1:inline]

Expert interpretation:

☐ OMI ☐ not-OMI ☐ Undefined

The second pre-PCI ECG

[ekg2:inline]

Expert interpretation:

☐ OMI ☐ not-OMI ☐ Undefined

The third pre-PCI ECG

[ekg3:inline]

Expert interpretation:

☐ OMI ☐ not-OMI ☐ Undefined

The fourth pre-PCI ECG

[ekg4:inline]

Expert interpretation:

☐ OMI ☐ not-OMI ☐ Undefined

The fifth pre-PCI ECG

[ekg5:inline]

Expert interpretation:

☐ OMI ☐ not-OMI ☐ Undefined

Are there any dynamic changes suggestive of OMI in pre-PCI ECGs ?

☐ Yes
☐ No
☐ Undefined

(Dynamic ST-T changes, Q wave development)

The first post-PCI ECG

[postpci_ekg:inline]

Post-PCI 24h ECG

[postekg24:inline]

Post-PCI 48h ECG

[postekg48:inline]

Post-PCI 72h ECG

[postekg72:inline]

Does ECG show evolution compatible with acute myocardial infarction ?

- ☐ Yes
☐ No
☐ Undefined

(Characteristic Q wave and/or ST normalization and/or T wave inversion)

Anjiyografi (Angiography)

Study ID#

Did the patient undergo angiography ?

☐ Evet ☐ Hayır

Date of angiogram
(As day-month-year and hour:minute)

Access site
(Vascular access site for primary PCI)

☐ Radial ☐ Femoral

Angina relieved before angiography ?

☐ Yes ☐ No ☐ Unknown

ST-segment elevation on monitor relieved before angiography ?

☐ Yes ☐ No ☐ Unknown

Infarct-related artery

☐ None
☐ LMCA
☐ LAD
☐ CX
☐ RCA
☐ Other or more than one

Enter the "other" artery
(IM, intermediary artery; D, diagonal artery; OM, obtuse marginal artery etc.)

Culprit looking lesion
(Select all that applies)

☐ Total occlusion with an impression of being acute
☐ >90% diameter stenosis
☐ Presence of thrombus
☐ Contrast staining
☐ Irregular borders suggesting ulcerated plaque

TIMI flow level before PCI to culprit lesion

☐ TIMI 0, No perfusion
☐ TIMI 1, No perfusion but penetration (contrast penetrates past the lesion, but cannot reach distal coronary bed)
☐ TIMI 2, Partial perfusion (contrast reaches to distal vascular bed, but entry, filling and clearance are slower than other vessels)
☐ TIMI 3, Complete perfusion (distal flow and clearance are the same as those in other vessels)

PCI to culprit lesion ?

☐ Evet ☐ Hayır

TIMI flow level after PCI to culprit lesion

☐ TIMI 0, No perfusion
☐ TIMI 1, No perfusion but penetration (contrast penetrates past the lesion, but cannot reach distal coronary bed)
☐ TIMI 2, Partial perfusion (contrast reaches to distal vascular bed, but entry, filling and clearance are slower than other vessels)
☐ TIMI 3, Complete perfusion (distal flow and clearance are the same as those in other vessels)

Additional lesions

(Select for diameter stenosis of >30% for LMCA and 50% for other vessels. Do not include chronic total occlusion.)

- ☐ LMCA
 - ☐ LAD
 - ☐ CX
 - ☐ RCA
 - ☐ Other lesions
 - ☐ None
-

Enter other additional lesions

(IM, intermediary artery; D, diagonal artery; OM, obtuse marginal artery etc. Multiple lesions should be separated with commas)

Vessels with chronic total occlusions

(Do not include infarct-related artery.)

- ☐ LMCA
 - ☐ LAD
 - ☐ CX
 - ☐ RCA
 - ☐ Other additional lesions
-

Enter other chronic total occlusions

(IM, intermediary artery; D, diagonal artery; OM, obtuse marginal artery etc.)

Any additional PCI ?

(The number vessels with non-culprit PCI at the same admission)

☐ 0 ☐ 1 ☐ 2 ☐ ≥3

Since the patient is excluded, you do not need to fill this form.

(If you think this is an error, please check your answer for "Has the patient been excluded ?" on the first form (Identification).)

Hastanedeki klinik değişkenler (In-hospital clinical parameters)

Study ID#

Upload post-PCI ECG
(if PCI not done, the first ECG at CCU)

Upload 24th hour ECG

Upload 48th hour ECG

Upload 72nd hour ECG

24h troponin level
(troponin level in ng/L [=pg/mL], e.g.; 12)

48h troponin level
(troponin level in ng/L [=pg/mL], e.g.; 12)

72h troponin level
(troponin level in ng/L [=pg/mL], e.g.; 12)

Ejection fraction
(Percentage, e.g.; 55)

Wall motion score
(Total point in 17-segment model, where
1=normokinesia, 2=hypokinesia, 3=akinesia)

Any other occlusion or re-occlusion during hospital stay ?

☐ Evet
☐ Hayır

Since the patient is excluded, you do not need to fill this form.
(If you think this is an error, please check your answer for "Has the patient been excluded ?" on the first form (Identification).)

Çıkış bilgileri (Clinical parameters on discharge)

Study ID#

Recommend allowing access for physicians to e-pulse account.
(For easy access to long-term follow-up).

In-hospital intubation after randomization

☐ Evet ☐ Hayır

In-hospital cardiopulmonary resuscitation after randomization

☐ Evet ☐ Hayır

In-hospital mortality after randomization

☐ Evet ☐ Hayır

Final diagnosis

(If preliminary diagnosis is confirmed, select "Myocardial infarction". If the patient was enrolled with a preliminary diagnosis of MI, but myocardial injury has been accounted for another reason later on, then select "Other troponin elevations". If no troponin rise observed, select "Other". If the patient died before any troponin result could be obtained, decide according to clinical scenario).

☐ Myocardial infarction
☐ Other troponin elevations (Heart failure, myocarditis, pulmonary embolism etc.)
☐ Other

Aspirin
(Prescribed medications on discharge)

☐ Evet ☐ Hayır

P2Y12 inhibitors
(Prescribed medications on discharge)

☐ None
☐ Clopidogrel
☐ Ticagrelor
☐ Prasugrel

OAC/NOAC
(Prescribed medications on discharge)

☐ Evet ☐ Hayır

ACEi/ARB
(Prescribed medications on discharge)

☐ Evet ☐ Hayır

ARNI
(Prescribed medications on discharge)

☐ Evet ☐ Hayır

SGLT2i
(Prescribed medications on discharge)

☐ Evet ☐ Hayır

Beta-blocker
(Prescribed medications on discharge)

☐ Evet ☐ Hayır

Calcium channel blocker
(Prescribed medications on discharge)

☐ Evet ☐ Hayır

MRA
(Prescribed medications on discharge)

☐ Evet ☐ Hayır

Loop diuretic
(Prescribed medications on discharge)

☐ Evet ☐ Hayır

Statin
(Prescribed medications on discharge)

☐ Evet ☐ Hayır

Since the patient is excluded, you do not need to fill this form.

(If you think this is an error, please check your answer for "Has the patient been excluded ?" on the first form (Identification) or "In-hospital mortality?" in Discharge data form.)

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Takip ve sonlanım (Long-term follow-up)

Study ID#

Long-term hospitalization
(Hospitalization in the first year)

☐ Evet ☐ Hayır

Date of hospitalization
(The first hospitalization after discharge)

Was the reason for hospitalization cardiovascular in origin ?

☐ Yes ☐ No ☐ Unknown

Due to coronary by-pass surgery ?
(Direct transfer after index admission or planned surgery after discharge)

☐ Evet ☐ Hayır

Was the cause of admission PCI ?
(Can be an elective or emergent admission.)

☐ Evet ☐ Hayır

Was this PCI planned ?
(Can be an elective or emergent PCI.)

☐ Evet ☐ Hayır

Long-term mortality
(Mortality in the first year after discharge)

☐ Evet ☐ Hayır

Mortality date

Was the reason for death cardiovascular in origin ?

☐ Yes ☐ No ☐ Unknown

You do not need to input any data to this form, since the patient has been excluded from the study.
(If you think this message is inappropriate, check your response to "Has the patient been excluded ?" (in Identification form).)