

Main-Title: Target Investigation of Residual Inflammation after Non-ST/ ST Elevation Acute Coronary Syndrom - TIRANA (ACS) Prospective REGISTRY

Field	Description
Study Title	<p>Neutrophil/Lymphocyte Ratio as an Important Predictor of Mortality in Post-Acute Coronary Syndrome Patients</p> <p>This prospective observational study aims to evaluate the prognostic significance of the neutrophil-to-lymphocyte ratio (NLR) as a predictor of mortality in patients following an episode of Acute Coronary Syndrome (ACS). Despite advancements in interventional cardiology and medical therapy, mortality remains significant in post-ACS patients, and early risk stratification is essential for optimizing outcomes.</p> <p>Recent studies have suggested that systemic inflammatory markers, such as NLR, are associated with adverse cardiovascular events. It is an easily obtainable and cost-effective laboratory parameter derived from a routine complete blood count. However, its value as an independent predictor of mortality post-ACS has not yet been fully established in our population.</p> <p>The study will include patients aged, admitted with a confirmed diagnosis of ACS (STEMI or Non-STEMI) and treated with percutaneous coronary intervention (PCI). NLR values will be measured from the first blood draw upon hospital admission, 24 and 48 hours post PCI. Patients will be followed up for up to 6 months after discharge through telephone interviews .</p>
Brief Summary (max 500 words)	<p>First, primary outcomes of the study will be the association between NLR values and mortality (all cause mortality and cardiovascular mortality), MACE (MACE was defined as the composite of all-cause mortality, cardiac death, unplanned revascularization, non-fatal myocardial infarction that was attributable and not related to stent failure or unplanned revascularization not related to stent failure) within 6 months post-ACS.</p> <p>Secondary outcomes will include:</p> <ol style="list-style-type: none">Differences in mean NLR between STEMI and NSTEMI patients.Association between elevated NLR and the presence of multivessel coronary artery disease on angiography.Correlation of NLR with other biomarkers, including the platelet-to-lymphocyte ratio (PLR), C-reactive protein (CRP), high-density lipoprotein (HDL) cholesterol, and maximum troponin levels (as an indicator of myocardial infarction size) <p>This study aims to contribute to the identification of easily accessible and cost-efficient biomarkers that can aid clinicians in early risk stratification of ACS survivors. A strong correlation between high NLR values and increased post-</p>

discharge mortality would suggest that inflammation plays a key role in patient prognosis and could potentially influence post-ACS management strategies.

Methodology:

Objective: To evaluate the neutrophil-to-lymphocyte ratio (NLR) as a significant predictor of mortality in patients post-acute coronary syndrome (ACS).

Specific Aims:

- 1.To assess the correlation between the NLR and in-hospital death, as well as 6-month mortality, in post-ACS patients.
- 2.To determine the correlation between the NLR and the presence of multivessel coronary disease on angiography, as well as with PLR, C-reactive protein (CRP) levels, and high-density lipoprotein (HDL) cholesterol levels.
- 3.To evaluate the correlation between the NLR and maximum troponin levels (as an indicator of myocardial infarction size).

Data Collection:

Detailed
Description

General patient information, diagnosis, comorbidities, CRP levels, neutrophil and lymphocyte counts, thrombocyte count, HDL cholesterol, LDL cholesterol, and complications (electrical and mechanical) will be collected from the medical records in the cardiology department of our main tertiary hospital “Mother Teresa Hospital”.

Angiographic data and treatment information will be gathered from standard coronary angiography reports used at our cardiac catheterization laboratories.

The follow-up form used for telephone interviews with patients is based on standardized instruments, including the WHO Rose Angina Questionnaire, Seattle Angina Questionnaire, EQ-5D-5L, MacNew Heart Disease Health-Related Quality of Life Questionnaire, McGill Pain Questionnaire, and the MRC Dyspnoea Scale.

Patient status will be evaluated at 24 hours, 48 hours, and 6 months after the onset of symptoms. The symptom onset time will be obtained from medical records documented upon patient referral.

Study Type
Study Phase

Prospective observational
Not Applicable

Study Design

Observational Model: Cohort
Time Perspective: Prospective
Number of Groups: 2 (STEMI and NSTEMI patients)

This is a retrospective observational cohort study evaluating the prognostic value of the neutrophil-to-lymphocyte ratio (NLR) in predicting 6-month mortality in patients who underwent PCI following an acute coronary syndrome.

Conditions Acute Coronary Syndrome
Interventions Not Applicable

Primary Outcome : Association Between Neutrophil-to-Lymphocyte Ratio (NLR) and Mortality (all cause mortality and cardiovascular mortality), MACE (MACE was defined as the composite of all-cause mortality, cardiac death, unplanned revascularization, non-fatal myocardial infarction that was attributable and not related to stent failure or unplanned revascularization not related to stent failure) in Post-Acute Coronary Syndrome (ACS) Patients

Description:

This outcome assesses the predictive value of NLR levels for mortality within 6 months following an ACS event.

Time Frame: 6 months post-ACS with a potential prolonged period of roughly 12 months

Safety Issue: No

Secondary Outcome

1. **Outcome Measure Title:** Difference in Mean NLR Between STEMI and NSTEMI Patients

Description: This outcome evaluates the variation in mean NLR values among patients diagnosed with ST-Elevation Myocardial Infarction (STEMI) versus Non-ST-Elevation Myocardial Infarction (NSTEMI).

Time Frame: At hospital admission

Safety Issue: No

2. **Outcome Measure Title:** Association Between High NLR and Presence of Multivessel Coronary Artery Disease

Description: This outcome explores whether elevated NLR values are associated with the presence of multivessel disease identified during coronary angiography.

Time Frame: During initial coronary angiography .

Safety Issue: No

3. **Outcome Measure Title:** Correlation Between NLR and Other Inflammatory Markers (PLR, CRP, HDL-Cholesterol)

Description: This outcome assesses the relationship between the NLR and other laboratory markers of inflammation and cardiovascular risk, including platelet-to-lymphocyte ratio (PLR), C-reactive protein (CRP), and HDL-cholesterol levels.

Time Frame: Within 48 hours of hospital admission

Safety Issue: No

4. **Outcome Measure Title:** Correlation Between NLR and Peak Troponin Levels

Description: This outcome evaluates the correlation between baseline NLR and peak troponin levels as a surrogate marker for myocardial infarction size.

Time Frame: During hospitalization (within first 5 days of admission)

Safety Issue: No

Outcome
Measures

Eligibility Criteria	<p>Inclusion Criteria: All patients (undergoing PCI, aged 18-85 years) presenting to the cardiology department or/and the cardiology intensive care unit with a diagnosis of ACS.</p> <p>Exclusion Criteria: Patients presenting to the cardiology department or/and the cardiology intensive care unit with diagnoses other than ACS and/or UA. Patients who died before undergoing PCI and those who did not provide a contact number.</p>
Locations	University Medical Center of Tirana "Mother Teresa". Planning to enroll in our registry also the University Clinical Center of Kosovo. Therefore a bicentric prospective ACS-Registry.
Sponsor/Collaborators	None
Responsible Party	Martiola Kola , Dr.Andi Rroku MD , Prof . Alban Dibra MD , Phd
IRB Approval	3232