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Can white blood cells predict death in heart attack patients?

Submission date
29/04/2020

Recruitment status
No longer recruiting

Registration date
12/05/2020

Overall study status
Completed

Last Edited
12/05/2020

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Acute myocardial infarction (heart attack) is a highly prevalent non-communicable disease with significant burden worldwide. Previous studies have shown that inflammation and immune cells play an important role in myocardial infarction. White blood cells include cells that are concerned with inflammation. These inflammation cells include neutrophils and lymphocytes which fight against bacteria and viruses. Changes of white blood cells have been used to predict complications in myocardial infarction. Several mechanisms could probably explain the role of neutrophils in atherosclerosis (narrowing of blood vessels by plaque) and myocardial infarction. Besides, lymphocytes play a role in the healing process. Some studies have suggested that eosinophils and basophils also may play a role. These cells are rich in small granules, which can be released that can favour thrombus (blood clot) formation and enhance vasoconstriction (narrowing of blood vessels) at the coronary (heart) level. Researchers have tried to evaluate the association between basophils and complications in patients with myocardial infarction. Recent research has pointed out the possible role of inflammation to the mechanisms behind heart attacks. The aim of this study is to examine the possible role of white blood cells in complications that might arise following a heart attack.

Who can participate?
Patients with new heart attacks

What does the study involve?
The study will involve data collection through reviewing participants' records and angiograms, and taking blood samples to identify white blood cells.

What are the possible benefits and risks of participating?
Participants will receive high-class treatments with frequent supervision. They will not receive potential new drugs or have to deal with new devices. Their participation is highly appreciated and will help to uncover some important points about inflammation, white blood cells and heart attacks.

Where is the study run from?
Cairo University (Egypt)

When is the study starting and how long is it expected to run for?
January 2019 to August 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Walid Ahmed
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
07032019

Study information

Scientific Title
Absolute and relative basophilic counts can predict major cardiac cerebrovascular events in ST-segment elevation myocardial infarction

Study objectives

Previous studies have shown that inflammation and immune cells play a critical role in acute ST-elevation myocardial infarction. This study evaluated the association between absolute and relative basophilic counts and in-hospital major adverse cardiac cerebrovascular events in patients with STEMI.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/03/2019, ethics committee of Cairo University (Critical Care Department, Faculty of Medicine, El Saray Street, Manial, Cairo, 11562, Egypt; +20 (0)122 310 3336; elhadidyamr@gmail.com), no ref provided

Study design
Retrospective observational study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Major adverse cardiac and cerebrovascular events and organ supportive measures

Interventions
A retrospective observational study was conducted on 607 patients admitted to the critical care department at Cairo University Hospitals with ST-elevation myocardial infarction from 2013 to 2017. They were candidates for primary PCI. These patients were managed according to published ESC guidelines at that time being.

All patients admitted to the critical care department with acute ST-elevation myocardial infarction were referred for primary percutaneous coronary intervention, if indicated, within a timely protocol. Those patients were subjected to thorough clinical history and physical examination to document cardiac status, Killip class, clinical compensation and to exclude possible complications. Written informed consent from the patient was obtained to allow for participation and data collection.

Routine laboratory tests including complete blood picture (CBC) on admission, second day, and third day and recording absolute and relative basophil counts. Lactate and hsCRP were measured on admission. The SYNTAX score was employed for risk stratification of patients undergoing revascularization.

Patients were followed up during their in-hospital stay for major adverse cardiac and cerebrovascular events (MACCEs) during the hospital stay. MACCEs included death, stroke, target vessel revascularization, and myocardial re-infarction). Patients were divided into two groups accordingly.

Procedure complications, which included no-reflow phenomenon (defined as resultant TIMI flow less than III), dissection, distal embolization, side branch occlusion, hematoma, failed PCI, and

retroperitoneal hematoma. Another recorded complication is contrast-induced nephropathy (CIN) defined as either a 25% increase in serum creatinine from baseline or a 0.5 mg/dL (44 µmol /L) increase in absolute serum creatinine value within 48-72 hours after intravenous contrast administration.

Complicated in-hospital course was defined as those patients who experienced medical complications that necessitated supportive specific ICU measures, including patients who needed respiratory support (invasive and non-invasive), hemodynamic support, or renal replacement therapy.

Blood sampling and the blood parameters; absolute and relative basophil counts were done using SYSMEX and CELLTEC devices System. The SYSMEX and CELLTEC devices used flow cytometric techniques to analyze the RBC, platelet, and WBC.

Intervention Type
Other

Primary outcome(s)
Major adverse cardiac and cerebrovascular events (MACCE) including death, myocardial infarction, stroke or target vessel revascularization. They were recorded during patient in-hospital stay through verifying medical records, laboratory values, ECG records and possible 2nd look angiograms. This was done during patient in-hospital course.

Key secondary outcome(s))
1. Organ supportive measures including patients who needed:
1.1. Respiratory support (invasive and non-invasive)
1.2. Hemodynamic support (vasopressors for persistent hypoperfusion state or mechanical assistance e.g. intra-aortic balloon pulsation)
1.3. Renal replacement therapy (dialysis for acute renal failure)
Collected through reviewing electronic records and vital signs sheets recorded during the whole hospital stay

Completion date
31/08/2020

Eligibility

Key inclusion criteria
Patients diagnosed with acute STEMI. Acute myocardial infarction was diagnosed upon detection of a rise and/or fall of cardiac biomarkers (preferably troponin) with at least one value above 99th percentile of the upper reference limit, together with evidence of myocardial ischemia with at least one of the following: symptoms of ischemia, ECG changes, development of pathological Q waves in ECG, or imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.
ECG criteria were based on changes in electrical currents of the heart (measured in millivolts). Typically, ST-segment elevation in acute myocardial infarction, measured at the J point, should be found in two contiguous leads and be ≥0.25 mV in men below the age of 40 years, ≥0.2 mV in men over the age of 40 years, or ≥0.15 mV in women in leads V2–V3 and/or ≥0.1 mV in other leads (in the absence of left ventricular (LV) hypertrophy or left bundle branch block (LBBB). In patients with inferior myocardial infarction, it is advisable to record right precordial leads (V3R and V4R) seeking ST elevation, in order to identify concomitant right ventricular infarction.

Likewise, ST-segment depression in leads V1–V3 suggests myocardial ischemia, especially when the terminal T-wave is positive (ST-elevation equivalent) and may be confirmed by concomitant ST elevation ≥0.1 mV recorded in leads V7–V9.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
607

Key exclusion criteria
1. Patients with evidence of an acute or chronic infection, hematological diseases, history of trauma or surgical operation within preceding 2 weeks
2. Patients diagnosed with immune system deficiencies, malignancies, autoimmune disorders or on immunosuppressive regimens including steroids

Date of first enrolment
01/01/2013

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Egypt

Study participating centre
Cairo University
Critical Care Department
Faculty of medicine
Manial
Cairo
Egypt
11562

Sponsor information

Organisation
Cairo University

ROR
https://ror.org/03q21mh05

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Study data is available upon request from Dr Walid Ahmed (walidkamel@cu.edu.eg). This includes Excel datasheets. Original data is stored in electronic databases. Consents were obtained from patients upon their admission to agree for participation in data collection activities. Patients with missing consents were excluded or contacted either implicit or explicit to ensure they agree to participate. Patients' identities were anonymized and coded according to their medical registered number to keep privacy and confidentiality.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes