

# Testing a personalized heart treatment for diverse patients in the UAE: The EmHeart Study

<b>Submission date</b> 08/10/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/10/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/02/2025	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study looks at how a specific gene, CYP2C19, affects the way a heart medication called clopidogrel works. Some people have variations in this gene that make the medication less effective, which can increase their risk of heart problems. The study aims to see if using genetic information to guide treatment can reduce these risks for patients in the UAE.

### Who can participate?

Any patient aged 18 or older who has symptoms of acute coronary syndrome (a type of heart problem) confirmed by a doctor, is scheduled to receive antiplatelet therapy, and has signed a consent form can participate.

### What does the study involve?

Participants will be randomly assigned to receive either the standard treatment or a treatment plan guided by their genetic information. They will be monitored to see if the genetic-guided treatment reduces the risk of heart problems and other adverse events.

### What are the possible benefits and risks of participating?

The potential benefit is a more effective treatment plan that could reduce the risk of heart problems. However, there may be risks, such as side effects from the medication or the possibility that the genetic-guided treatment may not be more effective than the standard treatment.

### Where is the study run from?

The study is being conducted at the United Arab Emirates University in Al-Ain, Abu Dhabi, UAE.

### When is the study starting and how long is it expected to run for?

January 2016 June 2024

### Who is funding the study?

The study is funded by the Ministry of Education (MOE) of the United Arab Emirates.

Who is the main contact?  
Professor Bassam R. Ali, Bassam.ali@uaeu.ac.ae

## Contact information

### Type(s)

Public, Principal Investigator

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

Nil known

## Study information

### Scientific Title

Evaluating the efficacy and safety of the CYP2C19-pharmacogenomic-guided clopidogrel treatment approach for acute coronary syndrome patients in the United Arab Emirates multi-ethnic population:

"The EmHeart Study"

### Acronym

Clopedogril-EmHeart study

### Study objectives

CYP2C19 genotype-guided use of oral antiplatelets compared to non-genotype-guided standard of care therapy would significantly reduce the risk of ischemic events and adverse events in CYP2C19 LOF variants carriers after the occurrence of ACS among a sample from the UAE population

### Ethics approval required

Ethics approval required

### Ethics approval(s)

1. Approved 29/06/2020, Abu Dhabi health Research and technology ethics committee (Abu Dhabi-UAE, Abu-Dhabi, 5674, United Arab Emirates; +971 24449822; admt@doh.gov.ae), ref: DOH/CVDC/2020/1187
2. Approved 21/09/2022, Abu Dhabi health Research and technology ethics committee (Abu Dhabi-UAE, Abu Dhabi, 5674, United Arab Emirates; +971 24449822; admt@doh.gov.ae), ref: DOH/CVDC/2022/1458
3. Approved 09/11/2023, Abu Dhabi health Research and technology ethics committee (Abu Dhabi, Abu-Dhabi, 5674, United Arab Emirates; +971 24449822; admt@doh.gov.ae), ref: DOH /CVDC/2023/1952
4. Approved 09/03/2022, MCME research and ethics committee (Mediclinic Corporate office-Dubai, UAE, Dubai, 123812, United Arab Emirates; +971 45122730; MCME-ResearchOffice@mediclinic.ae), ref: MCME.CR.213.MAIN.2021
5. Approved 05/04/2023, The United Arab Emirates University Human Medical Research Ethics Committee (Al-Ain, Abu-Dhabi, UAE, Al-Ain, Abu-Dhabi, 15551, United Arab Emirates; + 971 3 713 5900; research.office@uaeu.ac.ae), ref: SNA/FA/2020-14
6. Approved 27/10/2021, Abu Dhabi health Research and technology ethics committee (Abu Dhabi-UAE, Abu-Dhabi, 5674, United Arab Emirates; +971 24449822; admt@doh.gov.ae), ref: DOH/CVDC/2021/1519

### Study design

Interventional randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Safety, Efficacy

**Participant information sheet**

No participant information sheet available

**Health condition(s) or problem(s) studied**

Acute coronary syndrome (ACS)

**Interventions**

Randomized controlled trial, Patients taking anti-platelets were randomly allocated into either interventional or control arm. Patients were randomized based on automated software called castorEDC. Patients in the interventional arm were genotyped for CYP2C19 variants. If the patient was identified as CYP2C19 intermediate metabolizer (IM) or poor metabolizer (PM), the genetic report recommended switching clopidogrel to ticagrelor for at least three months. If the patient was a normal metabolizer (NM), rapid Metabolizer (RM), or ultra-rapid Metabolizer (URM), no changes were recommended. At the same time, patients from the control arm followed the standard of care for ACS management based on the physician's decision, without genetic testing (genetic testing done at the end of the study)

**Intervention Type**

Genetic

**Primary outcome measure**

Composite of major adverse cardiovascular events (MACE), including myocardial infarction (MI), ischemic stroke, definite stent thrombosis, severe recurrent ischemia (angina requiring PCI), or death within 12 months following the ACS event measured using patient records at baseline, 4 weeks, 12 weeks, and 12 months

**Secondary outcome measures**

Major or minor bleeding events, assessed according to the thrombolysis in myocardial infarction (TIMI) criteria measured using patient records and patient interviews at baseline, 4 weeks, 12 weeks, and 12 months

**Overall study start date**

01/01/2016

**Completion date**

22/06/2024

**Eligibility**

**Key inclusion criteria**

1. Arabian Gulf patients
2. Above 18 years old
3. Diagnosed with acute coronary syndrome (ACS)
4. Planned to take anti-platelets for at least one year

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

207

**Total final enrolment**

169

**Key exclusion criteria**

1. Patients with severe illness
2. Severe renal or hepatic impairment
3. Patients not expected to take dual anti-platelets for a minimum of one year
4. Patients taking long-term anti-coagulants
5. Patients with active tumors and currently under chemotherapy
6. Patients with active bleeding or history of significant bleeding in the past three months
7. Hematologic problems:
  - 7.1. WBC  $< 2 \times 10^9 /l$
  - 7.2. Platelet counts  $< 100 \times 10^9 /l$
  - 7.3. Hematocrit  $< 30\%$

**Date of first enrolment**

28/10/2021

**Date of final enrolment**

28/03/2023

**Locations****Countries of recruitment**

United Arab Emirates

**Study participating centre**  
**Tawam hospital**  
Al-Ain, Asharej street  
Al-Ain  
United Arab Emirates  
15258

**Study participating centre**  
**Mediclinic Hospital, Al-Ain**  
Al-Ain  
Al-ain  
United Arab Emirates  
14444

**Study participating centre**  
**The Medical Heart Center**  
Al-Ain, Abu-Dhabi  
Al-Ain  
United Arab Emirates  
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**Study participating centre**  
**Burjeel Day surgery center**  
Abu-Dhabi. UAE  
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## **Sponsor information**

**Organisation**  
United Arab Emirates University

**Sponsor details**  
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+971 800-8238  
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**Sponsor type**

University/education

**Website**

<https://www.uaeu.ac.ae/en/>

**ROR**

<https://ror.org/01km6p862>

## **Funder(s)**

**Funder type**

Not defined

**Funder Name**

Ministry of Education (MOE), United Arab Emirates (UAE).

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a peer reviewed journal

**Intention to publish date**

10/10/2024

**Individual participant data (IPD) sharing plan**

The de-identified individual participant data (IPD) collected from the study will be available upon reasonable request. Requests for data access should be directed to the corresponding author, and access will be granted upon approval from the study's funding body and the institutional review board (IRB) committee.

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**IPD sharing plan summary**

Available on request