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

Submission date
08/10/2024

Recruitment status
No longer recruiting

Registration date
16/10/2024

Overall study status
Completed

Last Edited
28/02/2025

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
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?
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Contact information

Type(s)
Public, Principal investigator

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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 Reserarch 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 Reserarch and technology ethics committee (AbuDhabi-UAE, AbuDhabi, 5674, United Arab Emirates; +971 24449822; admt@doh.gov.ae), ref: DOH/CVDC/2022/1458

3. approved 09/11/2023, Abu Dhabi health Reserarch 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 Coporate 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 Reserarch 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

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Acute coronary syndrome (ACS)

Interventions
Randomized controlled trial, Patients taking anti-platelets were randomly allocated into intro 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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

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 x 10^9 /l
7.2. Platelet counts <100 x 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
AbuDhabi
United Arab Emirates
130972

Sponsor information

Organisation
United Arab Emirates University

ROR
https://ror.org/01km6p862

Funder(s)

Funder type
Not defined

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

Results and Publications

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