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Using genetic testing to personalize heart treatment for patients undergoing stent procedures in Qatar

Submission date 01/05/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 07/05/2025	**Overall study status** Ongoing	
Last Edited 06/05/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Pharmacogenetics has shown that certain gene variants can significantly alter the effectiveness and safety of drugs such as clopidogrel, a widely used antiplatelet agent prescribed after percutaneous coronary intervention (PCI). Despite growing global evidence supporting the clinical value of pharmacogenetic testing, its routine integration into standard clinical practice in Qatar has not yet been achieved. This study aims to implement a pharmacogenetic-guided approach to personalize clopidogrel therapy in patients undergoing PCI and requiring dual antiplatelet therapy for 12 months. Specifically, it evaluates the use of a point-of-care (POC) genotyping device to detect CYP2C19 genetic variants that are known to influence clopidogrel metabolism. Based on the test results, treating physicians may modify the antiplatelet regimen according to evidence-based guidelines issued by the Clinical Pharmacogenetics Implementation Consortium (CPIC) and the Dutch Pharmacogenetics Working Group (DPWG).

Who can participate?
Patients aged over 18 years undergoing PCI at the Catheterization Laboratory, Heart Hospital, Hamad Medical Corporation, who are clinically indicated to receive dual antiplatelet therapy.

What does the study involve?
Participation involves a one-time genetic test using a rapid POC CYP2C19 assay (via a finger-prick blood sample) and clinical follow-up over a 12-month period. During this time, the study team will collect data on clinical outcomes, including cardiovascular events, medication adjustments, and any adverse effects.

What are the possible benefits and risks of participating?
The anticipated benefit is the potential for improved treatment effectiveness and reduced adverse drug reactions through personalized therapy. The genetic test poses no known physical risk, and all procedures follow international standards for ethical conduct and data protection. Participants will be provided with contact details for study coordinators to address any questions or concerns and will be assured of the confidentiality and secure handling of their personal and medical data.

Where is the study run from?
Qatar Precision Health Institute (QPHI)

When is the study starting and how long is it expected to run for?
October 2022 to February 2026

Who is funding the study?
It is funded by the Qatar Precision Health Institute (QPHI) in collaboration with Hamad Medical Corporation (HMC)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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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
Personalization of clopidogrel antiplatelet therapy in patients undergoing percutaneous coronary intervention in Qatar

Study objectives
The current project aims to provide a clinical implementation of personalized therapy for cardiovascular agents (clopidogrel) via the adoption of point-of-care pharmacogenomics (POC PGX) reactive testing to guide clopidogrel therapy.

Primary objectives:
1. The purpose of the study is to implement reactive PGx-testing in personalizing therapy of clopidogrel in patients with acute coronary syndrome (ACS)/coronary heart disease (CHD) via adopting POC PGx reactive testing for CYP2C19 variants
2. Assessing the clinical utility of pharmacogenomics-guided clopidogrel treatment in patients undergoing percutaneous coronary intervention (PCI) compared with the conventional non-pharmacogenetic-guided clopidogrel treatment in terms of enhancing patient outcome.

Secondary objectives:
1. Evaluating the cost-effectiveness of pharmacogenomic-guided antiplatelet treatment in Qatar
2. Investigate whether patients with CYP2C19 LOF alleles would benefit from alternative antiplatelet therapy (prasugrel and ticagrelor) or from manipulating clopidogrel dosing

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 30/10/2023, Medical Research Center- Hamad Medical Coorporation (Hamad Medical City - Hamad Medical Corporation, Doha, 3050, Qatar; +974 (0)70001383; rabdellatif@qf.org.qa), ref: None

2. Approved 19/10/2022, Institutional Review Board - Hamad Medical Corporation (Hamad Medical City - Hamad Medical Corporation, Doha, 3050, Qatar; +974 (0)40256410; irb@hamad.qa), ref: None

Study design
Prospective interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital, Medical and other records, Pharmacy

Study type(s)
Prevention, Safety, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Coronary artery disease

Interventions
The prospective observation trial included all patients undergoing PCI and requiring dual antiplatelet therapy for 12 months. The prospective genotype-guided strategy (intervention group) will be compared against a retrospective nontailored strategy (control group), which will be 1000 patients from 01/01/2017 to 01/10/2020. The patients in the intervention group will be recruited prospectively in the catherization lab at the heart hospital, HMC. Immediately after ACS diagnosis, eligible patients will be recruited into the study after signing written informed consent. At the time of admission, the genetic test will be performed as soon as possible, and the result will be reported within 24 h. Patients identified as carriers of at least one CYP2C19 LOF allele are considered to have an at-risk genotype and will receive ticagrelor as an alternative antiplatelet therapy. Non-carriers will continue with standard clopidogrel dosing as per the invasive cardiologist.

Intervention Type
Genetic

Primary outcome measure
1. Cardiovascular death: death from any cardiovascular cause or death not clearly attributable to a non-cardiovascular cause assessed using medical records within 1 year
2. ACS: diagnosis of acute myocardial ischemia (STEMI, non-STEMI) or unstable angina assessed using medical records within 1 year
3. Non-fatal stroke: neurological deficit of 24 hours or more with confirmation by Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) within 1 year

Secondary outcome measures
1. Rehospitalization and length of stay in the hospital recorded in electronic medical records (EMR) within 1 year
2. Markers of stent thrombosis or coronary ischemic event not related to stent thrombosis recorded in electronic medical records (EMR) within 1 year

Overall study start date
19/10/2022

Completion date
01/02/2026

Eligibility

Key inclusion criteria
1. Patients older than 18 years
2. Written consent from the patient or legally acceptable representative (LAR)
3. Indication for PCI
4. Require an antiplatelet therapy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
600

Key exclusion criteria
1. Major bleeding
2. Contraindication to the use of antiplatelet therapy
3. Pregnant females
4. Participating in other clinical trials on a medicinal product or blood donation for less than 3 months
5. Liver cirrhosis
6. Bone marrow transplantation
7. Advanced malignancy
9. Severe thrombocytopenia

Date of first enrolment
01/02/2023

Date of final enrolment
30/05/2025

Locations

Countries of recruitment
Qatar

Study participating centre
Heart Hospital, Hamad Medical Corporation
Hamad Medical City, Hamad Medical Corporation
Doha
Qatar
3050

Sponsor information

Organisation
Qatar Precision Health Institute

Sponsor details
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Sponsor type
Research organisation

Website
https://www.qphi.org.qa/

Funder(s)

Funder type
Research organisation

Funder Name
Qatar Precision Health Institute

Funder Name
Hamad Medical Corporation (HMC)

Results and Publications

Publication and dissemination plan

Intention to publish date
01/06/2025

Individual participant data (IPD) sharing plan
The dataset generated during and/or analysed during the current study will be stored in a non-publicly available repository

IPD sharing plan summary
Stored in non-publicly available repository