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Using genetic testing to personalize warfarin treatment after heart valve replacement surgery in Qatar

Submission date 03/05/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 14/05/2026	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 13/05/2026	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Warfarin is a medication taken by mouth that helps prevent blood clots. It is commonly prescribed for people after heart valve replacement surgery to reduce the risk of serious complications.

However, warfarin can be difficult to use safely. The difference between a helpful dose and a harmful one is small. It is also affected by other medications, and people respond to it very differently, so the correct dose can vary a lot from person to person.

In Qatar, doctors usually start patients on standard doses of warfarin after surgery. They then monitor blood clotting regularly using a test called the international normalized ratio (INR) and adjust the dose to keep it within a safe range. This makes managing warfarin treatment challenging.

Research has shown that a person’s genes can influence how much warfarin they need. Using genetic information could help doctors predict the right dose more accurately and make treatment safer.

This study looks at whether rapid genetic testing at the point of care can help guide warfarin dosing for patients after heart valve surgery. The goal is to improve dosing accuracy and support the routine use of personalized (genetics-based) treatment for warfarin in Qatar.

Who can participate?

Patients 18-75 years old who are indicated warfarin following heart valve replacement surgery, have not used warfarin in the past 3 months, and have have normal INR value of 0.8-1.2

What does the study involve?

The genetic testing-guided strategy (intervention group) of patients will be compared against a traditional dosing strategy (control group). In the intervention group the genetic test will be performed as soon as possible and the result will be reported 2 days before the surgery.

What are the possible benefits and risks of participating?

The study aims to implement pharmacogenetic testing in the clinical setting in Qatar, which helps in personalising anticoagulant therapy for more efficient treatment and fewer side effects.

No potential harm or anticipated risk is associated with participation. Participants would be provided with a point-of-contact in case they have any complications or adverse effects that they could report.

Where is the study run from?
Hamad Medical Corporation (Qatar)

When is the study starting and how long is it expected to run for?
January 2023 to May 2026

Who is funding the study?
Qatar Precision Health Institute (Qatar)

Who is the main contact?
Dr Rania Galal Abdel-latif, rabdellatif@qf.org.qa

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Dr Rania Abdel-latif

Contact details
Qatar Precision Health Institute-Qatar Science and Technology Park, Tech 1
Doha
Qatar
5825
+974 (0)70001383
rabdellatif@qf.org.qa

Additional identifiers

Study information

Scientific Title
Clinical implementation of pharmacogenetic-guided dosing of warfarin in patients with heart valve replacement in Qatar

Study objectives
This study is designed as a two-arm comparative study (prospective cohort study vs retrospective study). The study includes heart patients undergoing heart valve replacement and eligible for warfarin treatment post-surgery. The study is designed to demonstrate whether genotype-guided dose prediction improves the safety and efficacy of warfarin treatment compared to non-tailored strategies.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/09/2022, Hamad Medical Corporation (Hamad Medical City, Doha, 3050, Qatar; +974 (0)66480831; AElsid@hamad.qa), ref: IRB-HMC-2021-011

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Historical

Assignment
Sequential

Purpose
Health services research, Prevention

Study type(s)

Health condition(s) or problem(s) studied
Patients eligible for warfarin after heart valve replacement surgery

Interventions
The prospective cohort genotype-guided strategy (intervention group) of 150 patients will be compared against a traditional retrospective clinical dosing strategy (control group), which will be 300 patients from 01/01/2019 to 01/10/2022. The patients of the intervention group will be recruited prospectively in the heart hospital, Hamad Medical Corporation. Before being assigned to the surgery, eligible patients will be recruited in the study after signing written informed consent. The genetic test will be performed as soon as possible, and the result will be reported 2 days before the surgery.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Warfarin

Primary outcome(s)
1. The percentage of time in the therapeutic range (TTR) during a 30-day timeframe, measured using the percentage of the time the patient INR is within the target range during 30 days of therapy according to the method of Rosendaal, measured at 30 days post heart valve replacement surgery

2. The time to achieve the therapeutic INR during a 30-day timeframe, measured using the time from the initiation of warfarin therapy until the first INR reaches the treatment coagulation range, measured at 30 days post heart valve replacement surgery

Key secondary outcome(s)
1. Time to reach stable warfarin dose, measured using serial INR monitoring and dosing records (stable dose is defined as an INR within the target therapeutic range on a specified dose maintained for at least 2 consecutive days), at clinical follow-up visits between day 5 and day 30 after warfarin initiation

2. Over-anticoagulation events measured using the incidence of INR >4.0 using laboratory INR testing at the first 4 weeks of follow-up after warfarin initiation

3. Under-anticoagulation events measured using the incidence of INR <2.0 using laboratory INR testing at the first 4 weeks of follow-up after warfarin initiation

4. Frequency of warfarin dose adjustments measured using prescribing and medication records by counting the number of dosage changes at the first 4 weeks after warfarin initiation

5. Minor bleeding, major bleeding, and hemorrhagic complications measured using clinical assessment and electronic medical record documentation (bleeding events will be classified according to standard clinical definitions) at the first 4 weeks after warfarin initiation

6. Thromboembolic events, recurrent thrombosis, and stroke incidence as indicators of lack of anticoagulation efficacy, measured using clinical assessment, imaging reports, and electronic medical record documentation at the first 4 weeks after warfarin initiation

7. Warfarin sensitivity incidence measured using warfarin dosing records (warfarin sensitivity is defined as a stable maintenance dose of 1.5 mg/day or less on three successive clinic visits) at clinical follow-up visits within the study period

Completion date
03/05/2026

Eligibility

Key inclusion criteria
1. 18-75 years old
2. Not used warfarin in the past 3 months
3. Normal international normalised ratio (INR) value of 0.8-1.2
4. Informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
25

Key exclusion criteria
1. History of any other cardiac operation
2. Diagnosis of active cancer/haematological disorders
3. Severe renal/hepatic insufficiency
4. Abnormal thyroid function
5. Pregnancy
6. Inability to provide written consent

Date of first enrolment
22/01/2023

Date of final enrolment
04/10/2025

Locations

Countries of recruitment
Qatar

Sponsor information

Organisation
Qatar Precision Health Institute

Funder(s)

Funder type

Funder Name
Qatar Precision Health Institute

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	version 1		05/05/2026	No	No
Protocol file	version 1		05/05/2026	No	No