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Using genetic testing to guide psychiatric medication prescribing

Submission date
20/05/2026

Recruitment status
Recruiting

Registration date
02/06/2026

Overall study status
Ongoing

Last Edited
21/05/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Globally, mental illness poses a huge healthcare challenge, affecting millions of people clinically and economically. A variety of responses and outcomes are observed with the use of different psychotropic medications, with different rates of overall remission from schizophrenia, depression, or bipolar disorder. Drug response can be enhanced through effective dosing and the mitigation of adverse drug reactions by incorporating pharmacogenetic testing into clinical workflows. The Food and Drug Administration (FDA), Clinical Pharmacogenetics Implementation Consortium (CPIC), and the Dutch Pharmacogenomic Working Group (DPWG) have established pharmacogenetic guidelines for several drug-gene pairs, including CYP2D6, CYP2C19, CYP2C9, CYP1A2, CYP3A4 and HLA-A/HLA-B gene variants, which may influence and predict drug responses. Genetic data with established analytical and clinical validity can be used to improve the trial-and-error approach in psychiatry so that patients are prescribed the appropriate drugs at the right dosage. The ultimate objective of this project is for psychiatrists to use pharmacogenetic information to accurately predict the effects of psychotropic medications on their patients to mitigate the "trial-and-error" procedures during diagnosis and treatment.

Who can participate?
Arab adult patients with a diagnosis of MDD or schizophrenia who are considered for psychotropic medications will be recruited from a psychiatric hospital. Arab origin: This study focuses on identifying genetic variants and their clinical implications specific to the Arab population. Inclusion of only Arab participants minimizes genetic heterogeneity, ensuring valid, population-specific findings that can directly inform precision medicine initiatives for this community. The Arab population is identified based on their nationality following the Qatar Biobank (QBB) protocol.

What does the study involve?
This initiative uses pharmacogenetic data, which may enhance patient clinical outcomes suffering from mental illness, based on clinical guidelines and validated genetic data. Participants will be recruited for 2 years. Eligible participants will be invited to donate biological samples to be genetically analyzed by Qatar Precision Health Institute (QPHI) to provide genetically guided antipsychotic medication prescriptions.

What are the possible benefits and risks of participating?
Benefits and risks not provided at time of registration

Where is the study run from?
Qatar Genome Program (QGP)/ QPHI

When is the study starting and how long is it expected to run for?
April 2026 to August 2029.

Who is funding the study?
QPHI

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

Contact information

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Scientific, Principal investigator

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Study information

Scientific Title

Clinical implementation of preemptive pharmacogenomics-guided prescription in psychiatry

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/08/2025, Hamad Medical Corporation (Hamad Medical City, Medical research Center, Hamad Medical corporation, Doha, 3050, Qatar; +97470001383; irb@hamad.qa), ref: MRC-01-25-466

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Sequential

Purpose
Health services research, Prevention

Study type(s)

Health condition(s) or problem(s) studied
Patients with a diagnosis of major depressive disorder (MDD)or schizophrenia

Interventions
This is a prospective cohort study to evaluate the effectiveness and clinical utility of the PGx testing in enhancing
medication safety and tolerability in 150 Arab patients diagnosed with MDD and schizophrenia recruited during their clinic
visit (in clinical settings of inpatients, outpatients or community) to HMC Psychiatry Hospital. Eligible participants will provide a 2 ml saliva sample during their clinical visit for DNA extraction and genotyping using a genotyping array in the QBB facility, where QGP will be responsible for genotyping, data analysis, validation of procedure and data profiling.

Patients will receive their treatment as part of the routine medical care and will be followed up for 2-4 weeks for early response. Patients who fail to achieve an early response to the initial treatment plan based on clinical judgment and/or based on a clinical rating scale are considered for PGx-guided prescription.

Meanwhile, genetic data will be provided and interpreted. Clinical recommendations will be issued based on current
evidence of international guidelines. The recommendations will be conveyed to the clinical pharmacists to evaluate these
recommendations in the context of the patient's current medication (to evaluate drug-drug interaction and drug-drug-
gene interaction), medical, and laboratory data.

Following the assessment, a personalized PGx report with the genetic test results will be incorporated into the patient's electronic health record. The clinical recommendations will also be shared with the treating physician for consideration. After the initial follow-up period, a patient who showed poor response or intolerance during the initial follow-up period (4 weeks) is going to be prescribed a new therapy based on their PGx recommendation.

Patients who will receive PGx-guided prescription will be followed up for 12 weeks (2 nd follow-up) and assessed for early
response at weeks 2and 4 and remission at weeks 8 and 12. Clinical information and treatment data that are required for
the research will be collected during the study and during the follow-up period.

Intervention Type
Genetic

Primary outcome(s)
1. Clinical effectiveness of antidepressant/antipsychotic pharmacotherapy: Symptoms of depression measured using the Montgomery-Asberg Depression Rating Scale (MADRS) at therapy initiation, 2-4 weeks, and 8-12 weeks

2. Clinical effectiveness of antidepressant/antipsychotic pharmacotherapy: Psychiatric symptoms (e.g., schizophrenia, psychosis) measured using the Brief Psychiatric Rating Scale (BPRS) at therapy initiation, 2-4 weeks, and 8-12 weeks

3. Clinical effectiveness of antidepressant/antipsychotic pharmacotherapy: Side effects of antipsychotic medications measured using the Glasgow Antipsychotic Side-Effect Scale (GASS) at therapy initiation, 2-4 weeks, and 8-12 weeks

4. Clinical effectiveness of antidepressant/antipsychotic pharmacotherapy: Side effects of antidepressant medications measured using the Antidepressant Side-Effect Checklist (ASEC) at therapy initiation, 2-4 weeks, and 8-12 weeks

Key secondary outcome(s)

Completion date
30/08/2029

Eligibility

Key inclusion criteria
1. Adult of age 18-65
2. Arab origin: This study focuses on identifying genetic variants and their clinical implications specific to the Arab population. Inclusion of only Arab participants minimizes genetic

heterogeneity, ensuring valid, population-specific findings that can directly inform precision medicine initiatives for this community. We identify the Arab population based on their nationality following the QBB protocol.
3. Those who are diagnosed with MDD or Schizophrenia (new and previously diagnosed) or other related psychotic or mood disorders based on clinical Judgment
4. Those who are eligible for prescription of psychotropic medications
5. Provide a written consent for participation

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Current diagnosis of delirium
2. Current diagnosis of dementia
3. High suicide risk
4. Current diagnosis of amnestic
5. Current diagnosis of another cognitive disorder
6. Current diagnosis of an eating disorder
7. Participated in a clinical trial within the past month
8. Other acute serious psychiatric disorder other than depression and schizophrenia
9. Excessive consumption of alcohol and/or drugs
10. Severe acute or severe chronic somatic diseases
11. Pregnant or lactating women
12. Patients with a severe cognitive impairment, which affects adherence to therapy or the ability to sign the consent form
13. Patients with active cancers
14. Having renal failure or severe renal dysfunction identified by a glomerular filtration rate of less than 30 ml/min/1.73
m2
15. Having severe hepatic dysfunction defined by raised serum aminotransferase (x 3 folds of normal levels) and
hospitalized for hepatic disease
16. Patients with cardiac dysfunction defined by reduced left ventricular ejection fraction (LVEF less than 35) or significant QTc-interval prolongation more than 500

Date of first enrolment

12/04/2026

Date of final enrolment
30/08/2028

Locations

Countries of recruitment
Qatar

Sponsor information

Organisation
Qatar Precision Health Institute (QPHI)

Funder(s)

Funder type

Funder Name
Qatar Precision Health Institute (QPHI)

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?
Participant information sheet	version 1	14/08/2025	21/05/2026	No	Yes
Protocol file	version 1	14/08/2025	21/05/2026	No	No