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Ghana heart failure registry

Submission date 31/07/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 18/08/2023	**Overall study status** Completed	
Last Edited 09/04/2024	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims

Heart failure is a leading cause of disability and death globally. The number of people with heart failure in Ghana is increasing rapidly, but the characteristics of heart failure, the treatment patterns and survival in people with heart failure are unknown. In addition, the expertise and tools for diagnosing and appropriately managing heart failure are largely unavailable.

The occurrence of HF in Ghana is likely to continue rising due to the increasing disease that can lead to HF such as diabetes, high blood pressure and obesity, and the continuing presence of other causes of heart failure such as rheumatic heart disease and endomyocardial fibrosis.

Heart failure may simulate chest, liver, or kidney diseases leading to wrong diagnosis and management. Empowering health professionals with diagnostic tools, training, and management protocols will help improve patient outcomes.

The diagnosis of HF in most patients is primarily based on their clinical presentation due to the limited availability of diagnostic equipment. Ghana has few cardiologists who are mainly located in tertiary hospitals. In addition, there is a lack of HF education and training for physicians and other healthcare providers.

HF management teams or multidisciplinary teams (MDTs) for HF management are recommended for the care of HF patients, but, these teams are nonexistent in Ghana, and most health facilities lack resources for long-term patient follow-up, such as diagnostic equipment, dedicated HF clinics, and protocols.

A national network of HF management teams (NNHFMTs) will be established in Ghana to help mitigate the burden of HF. The NNHFMTs are tasked with building the capacity of both secondary and tertiary levels of care to promptly and effectively identify and manage HF by creating HF management teams (HFMTs), establishing a national registry for HF and HF clinics that will be integrated with routine clinical services to provide long-term follow-up and care. The establishment of HF clinics and a national registry will fill a significant gap in HF care and research by providing the largest most recent epidemiological, management patterns and medium-term outcomes data on HF.

The main aim of this study is to determine the epidemiological characteristics and medium-term outcomes of HF in Ghana. This will be achieved by outlining the epidemiological and clinical characteristics of HF patients in Ghana, identifying the underlying causes, evaluating the medium-term outcomes of HF in Ghana, and identifying the factors that predict hospitalisation and death in HF patients in Ghana.

Who can participate?
Adults and children aged 13 years and above who are admitted or referred to the cardiology outpatient clinics with heart failure

What does the study involve?
Patients presenting with HF established heart failure clinic or the emergency room will be recruited and evaluated according to a standardized protocol. Patients will then receive recommended treatment for heart failure after the diagnosis has been confirmed and followed up for 6 to 12 months. The HFMTs of the two leading teaching hospitals in Ghana will be trained and will, in turn, provide mentorship and training to the other collaborating hospitals.

What are the possible benefits and risks of participating?
The study will improve the quality and care of patients with HF in the participating institutions because diagnostic equipment for heart failure will become available as the study is integrated into routine clinics and the improvement in knowledge and skills of health personnel managing HF patients. Additionally, patients will benefit from some financial relief since some investigations will be done at zero cost to patients.
There is no immediate risk to the participants. Heart failure medications licensed for heart failure will be prescribed as standard treatment to all patients. No experimental or drugs unapproved by the Food and Drugs Authority of Ghana will be administered to any patients. The most common risks of heart failure medications are drug-specific side effects that may include low blood pressure, low blood sodium, low blood potassium, high blood potassium, headache, drowsiness, lethargy, cramps, bleeding, gastritis, vomiting, anorexia, nausea, rash, pruritus, and urticaria. Careful evaluation of predisposing factors for drug side effects will be done, and close monitoring will be done during treatment as usual standard care to reduce or mitigate the risk of side effects.

Where is the study run from?
Ghana Heart Initiative (Ghana)

When is the study starting and how long is it expected to run for?
July 2022 to June 2024

Who is funding the study?
This study is funded by Bayer through German International Cooperation

Who is the main contact?
1. Prof. Isaac Kofi Owusu, ikeowusu@yahoo.com
2. Dr Alfred Doku, adoku@ug.edu.gh (Ghana), a.doku@amsterdamumc.nl (Netherlands)

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Public

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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
Assessing and improving the care of heart failure patients in Ghana: a national network of heart failure management centers and teams

Study objectives
Available data on heart failure (HF) in Ghana is limited to individual centres. Our approach to HF management in Ghana relies on research data that have been observed and published from registries developed in advanced countries with different patient demographics and clinical profiles, diagnostic algorithms and therapeutic strategies that are most often difficult to implement because of a lack of resources and different population dynamics.

Documented information about the outcome of treatments for patients with HF, including follow-up, is very scarce in Ghana.
A study of the patterns and management of HF in Ghana will serve as a pedestal to create a national HF registry.
Establishing an HF registry will improve and develop the care of patients with HF and the diagnosis of HF by providing continuous information about the diagnosis and therapy.
Additionally, an HF registry will be a valuable tool for improving the management of patients with HF since it enables participating centres to focus on improving diagnosis and medical treatment through regular updates and guidance from mentors or cardiologists.

Through this pragmatic study, diagnostic equipment for heart failure will become available as the study is integrated into routine clinics, improve the knowledge and skills of health personnel in managing HF, and ultimately improve the morbidity and mortality outcomes of HF patients in Ghana.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/01/2023, Korle Bu Teaching Hospital Institutional Review Board (Research Office, Medical Directorate Central Admin Block Korle Bu Teaching Hospital PO Box, 77, Accra, GE-209, Ghana; +233 (0)302739510; rdo@kbth.gov.gh), ref: KBTH/MD/G3/22

Study design
Cross-sectional observational multi-centre multi-level study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)

Medical and other records

Study type(s)
Diagnostic, Treatment

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Heart failure

Interventions
Guideline-directed medical therapy (GMDT)

Approximately 5,000 patients presenting with heart failure to 9 hospitals including teaching, regional and municipal hospitals will be recruited and evaluated according to a standardized protocol, including the use of echocardiogram, electrocardiogram, chest x-ray, laboratory investigations and NT-proBNP test. Guideline-directed medical treatment of heart failure will be initiated for 6-12 months, and the medium-term outcomes of interventions, including rehospitalisation and mortality assessed. Patient data will be collated into a heart failure registry for continuous assessment and monitoring.

Intervention Type
Other

Primary outcome measure
The following primary outcome measures are assessed using patient data that will be collated into a heart failure registry at 6 and 12 months:
1. Epidemiological profile of heart failure in Ghana
2. Heart failure rehospitalisation in patients with heart failure
3. Number of deaths in patients with heart failure

Secondary outcome measures
The following secondary outcome measures are assessed using patient data that will be collated into a heart failure registry, unless otherwise stated, at 6 and 12 months:
1. Clinical characteristics of heart failure patients in Ghana
2. Treatment patterns of heart failure in Ghana
3. Causes of heart failure in Ghana using history, clinical signs, laboratory findings and imaging
4. Factors that predict rehospitalisation and death in heart failure patients in Ghana

Overall study start date
08/07/2022

Completion date
01/06/2024

Eligibility

Key inclusion criteria

1. Patients with confirmed heart failure
2. Patients 13 years or older
3. Willingness to participate in the study

Participant type(s)
Patient

Age group
Mixed

Lower age limit
13 Years

Sex
Both

Target number of participants
5000

Key exclusion criteria
Participants who are unwilling to participate in the study

Date of first enrolment
01/01/2023

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
Ghana

Study participating centre
Komfo Ankye Teaching Hospital
Department of Medicine and Therapeutics
Po Box 1934
Adum-Kumasi
Kumasi
Ghana
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Study participating centre
Korle Bu Teaching Hospital
Department of Medicine and Therapeutics
Guggisberg Avenue, Accra, Ghana

PO Box 77
Korle Bu
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Study participating centre
Effia Nkwanta Regional Hospital
Ghana Health Services
PO Box 229
Sekondi
Ghana
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Study participating centre
Kumasi South Hospital
Ghana Health Service
PO Box 1908
Kumasi
Ghana
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Study participating centre
Bono Regional Hospital
Ghana Health Service
PO Box 27
Sunyani
Ghana
-

Study participating centre
Presbyterian Hospital-Agogo
Presbyterian Health Services
PO Box 27
Asante-Akim
Ghana
-

Study participating centre
Tamale Teaching Hsopital
Salaga/Yendi Road

Tamale
Ghana
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Study participating centre
Ho Teaching Hospital
PO Box MA 374
Ho
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Study participating centre
Cape Coast Teaching Hospital
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Sponsor information

Organisation
Deutsche Gesellschaft für Internationale Zusammenarbeit

Sponsor details
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Sponsor type
Government

Website
https://www.giz.de/en/html/index.html

ROR
https://ror.org/00q08t645

Funder(s)

Funder type
Government

Funder Name
Deutsche Gesellschaft für Internationale Zusammenarbeit

Alternative Name(s)
German Corporation for International Cooperation GmbH, German Corporation for International Cooperation GmbH), GIZ

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
01/06/2025

Individual participant data (IPD) sharing plan
The dataset generated and/or analysed during the current study will be available on request from Dr Alfred Doku (adoku@ug.edu.gh, a.doku@amsterdamumc.nl).

The dataset will include age, gender, nationality, ethnicity, and religion, and be available from 01/07/2024. Consent is required and obtained from participants. Data anonymisation will be undertaken. Respondents' names, addresses and telephone numbers will not be captured in the database and birth dates will only be used to obtain ages and recorded into the database as ages in years. There are no ethical or legal restrictions.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	Participant information sheet and consent forms included	05/08/2023	07/08/2023	No	Yes
Protocol file		05/08/2023	07/08/2023	No	No
Protocol article		08/04/2024	09/04/2024	Yes	No