Research on improving diagnostics, risk stratification, and progression in patients with heart failure.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON57259

Source
ToetsingOnline

Brief title
STRATIFY-HF

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
heart disease, Heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Horizon Europe Research and Innovation Action Programme

Intervention

Keyword: Diagnostics, Heart failure, Monitoring

Outcome measures

Primary outcome

The main endpoints of the diagnostic study performed in the Netherlands is the number of new HF diagnoses, and the demographic and clinical predictors of risk, diagnosis and progression of HF. The risk stratification is based on multiple elements with as key elements the MACE, hospitalization for HF or other cardiovascular diseases, and developing HF during follow-up. Ultimately, the DSS will be developed to predict the risk of developing HF.

Secondary outcome

Secondary clinical endpoints include:

- Quality of life measured using the Minnesota Living with Heart Failure (MLHFQ) questionnaire and the Short Form-36 questionnaire

- Major adverse cardiovascular event (MACE), including acute myocardial infarction, stroke, cardiovascular mortality and hospitalization for unstable angina or revascularization procedures (26).

- Heart failure hospital admission during the follow-up period.

- Heart failure diagnosis during the follow-up period in those who at baseline had no HF.

- Cardiac Output Response to Stress (CORS) test for HF diagnosis.

- Voice recording test for HF diagnosis.

Study description

Background summary

Heart failure (HF) is a complicated disease with low quality of life and high healthcare costs. General Practitioners (GPs) and cardiologists have no access to adequate risk stratification tools to further enhance their clinical judgement on HF.

Study objective

The aim of this clinical study-part in the Netherlands is to identify demographic and clinical predictors of risk, diagnosis, and progression of heart failure. In the European study component, the objective is to eventually compute with this consortium a STRATIFYHF artificial intelligence (AI)-driven Decision Support System (DSS) and mobile application for risk prediction, diagnosis, and progression of HF. This DSS will have partly been developed from an analysis of retrospective data assembled over 2023-24.

Study design

The present study is a cross-sectional diagnostic study with two years follow-up. The study population in the Netherlands consists of patients with suspected new-onset non-acute HF who are referred to the cardiologist by their GP. We aim to include 200 patients in the Sint Jansdal hospital in Harderwijk over 12 months, with a follow-up period of 24 months. Patients will receive standard care and will undergo several additional diagnostic tests at baseline (see section on study procedures). Based on the results of these tests at baseline, participants will fall into two groups, with and without HF.

Overall, eight clinical centers around Europe will recruit a total of 1,600 patients (200 patients per center, approximately 50% females). This study will collect data from the following centers:
- St Jansdal Harderwijk in cooperation with the Department of General Practice & Nursing Science of the Julius Center for Health Sciences and Primary Care, UMC Utrecht, Utrecht;
- Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle upon Tyne UK;
- University Hospitals Coventry and Warwickshire, Coventry UK;
- Cambridge University Hospitals NHS Foundation Trust UK;
- University Medical Centre Regensburg, Regensburg Germany;
- Careggi University Hospital, Florence Italy;
- Institute of Cardiovascular Diseases of Vojvodina, Sremska Kamenica, Novi Sad Serbia;
- Hospital Universitario Ramón y Cajal, Madrid Spain.

In this study, 800 patients (including those in the Netherlands, Newcastle, Coventry, and Cambridge) will be recruited from primary care settings individuals with suspected new-onset non-acute HF. The remaining 800 patients, recruited from secondary care settings in Regensburg, Florence, Novi Sad, and Madrid, will already have a diagnosis of HF. Each center has their own protocol adjusted to national possibilities. The follow-up data will be collected at 12 and 24 months.

In the Netherlands we will collect the data in our own secure database. Coventry University will collate and unify the data from the clinical partners, including data from our center, into a single prospective individual patient database (IPD) and data will be analysed using IPD (meta-)analytical techniques. Subsequently, they will share the data with the technical partners of the study to answer the secondary objectives. These technical partners include Bioengineering Research and Development Center (BIOIRC) in Serbia and Foundation for research and technology (FORTH) in Greece.

Study burden and risks

The research assessments depends solely on non-invasive and non-experimental investigations. Therefore, the burden associated with participation will be relatively low. Included patients after 1 year will be asked for (some) repeated questionnaires. At 12 and 24 months follow-up for each enrolled patient will be determined through the general practitioner and/or cardiologist whether a hospital admission or major adverse cardiac event (MACE) has occurred. Minors and persons with severe cognitive impairment or who are not proficient in Dutch will not be included.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Referred from primary care to cardiologist care with new-onset non acute heart failure
2. Age 45 years or over
3. Willing to sign informed consent
4. Able to provide written informed consent

Exclusion criteria

1. Inability to provide verbal informed consent
2. Not proficient in Dutch or having severe cognitive impairment (i.e. not able to understand and correctly
fill in the questionnaire or informed consent)
3. Presenting with severe symptoms (hospitalisation, natriuretic peptides > 2000 ng/L)
4. Terminal cancer diagnosis, receipt of oxygen therapy, or oxygen saturation at rest <92%
5. Recent acute coronary syndrome (within the last 60 days)
6. Severe physical disability preventing independence
7. Scheduled or implanted pacemaker or cardio-defibrillator within the last 3 months
8. Severe renal insufficiency (estimated eGFR <=15 or on dialysis)
9. Current or planned pregnancy
10. Life expectancy less than 12 months.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	200
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	16-01-2025
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT06377319
CCMO	NL86984.041.24