

Quality of adherence to guideline recommendations for life-saving treatment in heart failure: an international survey

Submission date 05/02/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/05/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/06/2023	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Heart failure (HF) is associated with a high mortality and morbidity, reduced quality of life, and increasing health care costs in Europe as well as across the world. The prescription of evidence-based therapies recommended by guidelines is the most effective way of ensuring that patients receive high-quality and optimal care. Surveys of patients with HF often provide descriptions of the clinical characteristics and management of patients and of outcomes, but we lack data on the use of guideline-recommended therapies in all potentially eligible patients. This is the aim of this study.

Who can participate?

Adult outpatients with chronic HF and left ventricular systolic dysfunction (LVSD).

What does the study involve?

Physician selection is based on the best available sources, either local or regional, concerning the epidemiology and medical care data, including available market data and epidemiological surveys. A general target of 10-20 consecutive patients per investigator was used ensuring the best possible representative inclusion of the HF population in each practice setting.

Information collected includes: demographics; medical history; risk factors and lifestyle; results of physical examination; current symptoms; laboratory values if available; and current medical treatments. Adherence to evidence-based pharmacologic treatments recommended by guidelines will be determined by calculating the adherence score, taking into account the treatment eligibility criteria and the existence of contraindications to drugs based on the international guidelines on management of HF.

What are the possible benefits and risks of participating?

This information is expected to be important to physicians, care providers, and health services, by identifying gaps between evidence and practice and areas for improvement in the post-discharge care of outpatients with chronic HF and LVSD. Physicians have been instructed to continue management and treatment of patients according to their usual practice and the new international guidelines for the management of HF. No specific tests or therapies will be

prescribed as part of this survey, and the management of patients will be completely left to the discretion of participating physicians.

Where is the study run from?
547 centres from 36 countries

When is the study starting and how long is it expected to run for?
January 2013 to September 2018

Who is funding the study?
Servier (France)

Who is the main contact?
Professor Michel Komajda

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
QUALITY of adherence to guideline recommendations for LIfe-saving treatment in heart failure: an international survey: an observational study

Acronym
QUALIFY

Study objectives

1. Assess clinical characteristics and management of outpatients with heart failure
2. Focus on how monitoring of disease status can be used to guide treatment

3. Evaluate the prescription of recommended therapeutic options in eligible patients
4. Assess adherence to the new European Society of Cardiology guidelines for the management of heart failure

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval obtained in every country in accordance with local regulations. All 557 centres obtained ethics approval before recruitment of the first participant (the first approval was obtained on 10/06/2013 from the Ethics Committee at the National Institute of Cardiovascular Diseases, Slovakia; approval for the last site was on 20/09/2014 from McGill University Health Centre Biomedical D, Canada).

Study design

Prospective observational longitudinal survey

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Heart failure

Interventions

Non-interventional survey

Intervention Type

Other

Primary outcome(s)

- 1 To evaluate physician's adherence to HF guidelines by measuring prescriptions modalities of recommended HF medications
2. To calculate an adherence score
3. To analyze the reasons for non-adherence
4. To assess the impact of adherence level on clinical outcomes

Measured at baseline and at 6, 12 and 18 months.

Key secondary outcome(s)

To characterize the clinical characteristics and management of outpatients with HF and left ventricular systolic dysfunction (LVSD).

Measured at baseline and at 6, 12 and 18 months.

Completion date

01/09/2018

Eligibility

Key inclusion criteria

Outpatients with chronic heart failure:

1. > 18 years of age
2. Hospitalised for worsening of heart failure within 1–15 months
3. With LVSD as demonstrated by left ventricular ejection fraction $\leq 40\%$ measured using the most recent echocardiogram (≤ 2 years)
4. Validation of rhythm at inclusion

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Patients on waiting list for heart transplantation or planned implantation of left ventricular assist device; planned cardiac resynchronisation therapy and implantable cardioverter defibrillators are permitted
2. Patients with planned revascularisation
3. Patients hospitalised for cardiovascular disease within the past 4 weeks
4. Conditions hampering participation or the 18-month follow-up

Date of first enrolment

01/09/2013

Date of final enrolment

30/12/2014

Locations

Countries of recruitment

Armenia

Australia

Austria

Azerbaijan

Bahrain
Belarus
Brunei Darussalam
Canada
China
Denmark
Egypt
Georgia
Germany
Greece
Hungary
Ireland
Jordan
Kazakhstan
Korea, South
Kuwait
Lebanon
Lithuania
Malaysia
Morocco
Oman
Poland
Portugal
Qatar
Romania
Russian Federation

Slovakia

Spain

Thailand

Türkiye

Ukraine

United Arab Emirates

Study participating centre

547 from 36 countries

France

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Sponsor information

Organisation

Servier

ROR

<https://ror.org/034e7c066>

Funder(s)

Funder type

Industry

Funder Name

Servier (France)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2016		Yes	No
Results article		10/02/2021	14/06/2023	Yes	No
Results article		30/04/2017	14/06/2023	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes